

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

PATRICIA WHITE, individually and as guardian of
TARAR CASSEL and TARAR CASSEL

(b) County of Residence of First Listed Plaintiff Philadelphia County, PA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Theodore C. Levy, Esq., Fine and Staud, LLC, 1333 Race
Street, Philadelphia, PA 19107

DEFENDANTS

LAUREL BROOK REHABILITATION AND HEALTHCARE
CENTER, ET AL.

County of Residence of First Listed Defendant Burlington County, NJ
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF
THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

William J. Mundy, Esq. Brian D. Pagano, Esq., Burns White
LLC, 457 Haddonfield Rd, Ste. 510, Cherry Hill, NJ 08002

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff ☒ 3 Federal Question
(U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant ☐ 4 Diversity
(Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input checked="" type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/ Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 INTELLECTUAL PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <input type="checkbox"/> 880 Defend Trade Secrets Act of 2016 SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit (15 USC 1681 or 1692) <input type="checkbox"/> 485 Telephone Consumer Protection Act <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN (Place an "X" in One Box Only)

- ☐ 1 Original Proceeding ☒ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District (specify) ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. 1441, 28 U.S.C. 1442, 28 U.S.C. 1331

Brief description of cause:

Long term care facility professional liability/medical malpractice related to COVID-19

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

I. PROCEDURAL BACKGROUND

1. Plaintiffs, Patricia White, individually and as the guardian of Tarar Cassel and Tarar Cassel, commenced the herein Healthcare malpractice professional liability action in the Superior Court of New Jersey, Middlesex County, Law Division, as Civil Action No. MID-L-4591-21 via a Complaint and Affidavit of Merit on August 5, 2021. (A true and correct copy of Plaintiffs' Complaint and Affidavit of Merit are attached collectively hereto as Exhibit "A".)

2. Removing Defendant was served with the Complaint on August 6, 2021. (A true and correct copy of the Affidavit of Service is attached hereto as Exhibit "B"). Accordingly, this Notice of Removal is timely. 28 U.S.C. § 1446(b).

3. Upon information and belief, the documents attached as Exhibits "A", "B", "C", "D", and "E" constitute all of the pleadings, process, and orders which were filed in connection with the state court action.

4. As against Removing Defendant, the Complaint asserts professional negligence claims related to the September 2020 COVID-19 diagnosis of incapacitated Plaintiff, Tarar Cassel, while a resident at Laurel Brook, a long term care facility licensed by the State of New Jersey Department of Health. Exhibit "A" at ¶¶ 34, 50(f).¹

5. Removing Defendant now files the instant Notice to remove this matter to the United States District Court for the District of New Jersey, Trenton Vicinage, under 28 U.S.C. § 1441(a) and 28 U.S.C. § 1442(a)(1), as Plaintiffs' claims relate to the use and administration of COVID-19 covered countermeasures by a covered person under the Public Readiness and

¹ Plaintiffs have also brought claims against Co-Defendants, Community Options, Inc., Virtua Willingboro Hospital, Powerback Rehabilitation – Piscataway, John Doe Individuals #1-10 and ABC Corporations #1-10. Exhibit "A".

Emergency Preparedness Act (“PREP Act”), 42 U.S.C. §§ 247d-6d(d), 247d-6e (2020), therefore “arising under” federal law within the meaning of 28 U.S.C. § 1331, as well as actions of Responding Defendant undertaken at the direction of the federal government.

6. As required under 28 U.S.C. §1446(d), Removing Defendant will promptly file copies of this Notice of Removal and related papers with the Clerk for the Superior Court of New Jersey, Middlesex County, Law Division, and copies will be sent to all parties.

II. BASIS OF REMOVAL TO FEDERAL COURT

7. This case is removable under 28 U.S.C. § 1441(a) on the basis of “original jurisdiction” because Plaintiffs’ Complaint asserts a claim “arising under” federal law within the meaning of 28 U.S.C. § 1331 by virtue of the complete preemption under the PREP Act and the existence of an embedded substantial federal question under *Grable & Sons Metal Products, Inc. v. Darue Eng’g. & Mfg.*, 545 U.S. 308 (2005).

8. This case is further removable under 28 U.S.C. § 1442(a)(1), as Removing Defendant is being sued in connection with alleged acts undertaken at the direction of a federal officer.

9. An entire action may be removed if one claim is cognizable under a removal statute, regardless of the relationship between the removable claim and non-removable claims. *Nat’l Audubon Soc. v. Dept. of Water & Power*, 496 F.Supp. 499 (E.D. Cal 1980).

A. The Public Readiness and Emergency Preparedness (“PREP”) Act

10. The PREP Act, codified at 42 U.S.C. § 201, *et seq.*, grants healthcare providers and other covered persons immunity from suit and liability as to claims for injuries related to the use of approved countermeasures to respond to a national public health emergency, such as COVID-19.

11. The PREP Act is triggered when the Secretary of Health and Human Services (HHS) issues a declaration defining the scope and breadth of the PREP Act relevant to a particular public health emergency, like COVID-19. *See* 42 U.S.C. § 247d. The PREP Act empowers the Secretary of HHS to issue a declaration “recommending[] . . .the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures” against the subject disease or pandemic. Upon the issuance of such a Declaration, “covered persons” who administer or use “covered countermeasures” receive immunity and become “immune from the suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure” as defined by the Secretary of HHS. 42 U.S.C. § 247d-6d(a)(1).

12. A “covered person” includes, *inter alia*, a person or entity that is a “program planner” or a “qualified person.” 42 U.S.C. 247d-6d(i)(2)(B). A “program planner” is a defined as

a State or local government, including . . . a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with declaration under subsection (b).

42 U.S.C. § 247d-6d(i)(6). A “qualified person” is defined as a

licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed.

42 U.S.C. § 247d-6d(i)(2)(B)(iv). The PREP Act defines a “person” as “an individual, partnership, corporation, association, entity, or public or private corporation, including a federal, state, or local government agency or department.” 42 U.S.C. § 247d-6d(i)(5).

13. On March 17, 2020, the HHS Secretary issued a Declaration establishing that as of February 4, 2020, “[l]iability immunity as prescribed by the PREP Act is in effect” for any “recommended activities” related to “[a]ctivities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasures following a Declaration of an emergency” related to COVID-19. Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020), *amended by* 85 Fed. Reg. 21012 (Apr. 15, 2020), 85 Fed. Reg. 35100 (June 8, 2020), 85 Fed. Reg. 52136 (Aug. 24, 2020), 85 Fed. Reg. 79190 (Dec. 9, 2020), 85 Fed. Reg. 7872 (February 2, 2021), 86 Fed. Reg. 9516 (February 16, 2021), 86 Fed. Reg. 14462 (Mar. 16, 2021) *and* 86 Fed. Reg. 41977 (Aug. 4, 2021) (herein, “the Declaration”).

14. The Declaration defines the term “administration” to include actions beyond the physical distribution of COVID-19 countermeasures to

activities and decisions directly relating to public and private delivery, distribution and dispensing of countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for [the] purpose of distributing and dispensing countermeasures.

85 Fed. Reg. 15202; *see also*, Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 85 Fed. Reg. 79190 (Dec. 9, 2020) (hereinafter “the Fourth Amendment to the Declaration”).

15. On October 23, 2020, HHS issued “Advisory Opinion 20-04 on the Public Readiness and Emergency Preparedness Act and Secretary's Declaration Under the Act” reiterating that “administration” under the PREP Act encompasses activities related to “management and operation” of COVID-19 countermeasure programs and those facilities that provide countermeasures to recipients. (A copy of Advisory Opinion 20-04 is attached hereto as Exhibit “F”). Advisory Opinion 20-04 expressly rejected the prior ruling in *Casabianca v. Mt. Sinai Medical Center*, 2014 WL 10413521 at *1 (N.Y. Sup. Ct. Dec. 12, 2014), attached hereto as Exhibit “G”, which improperly held that the PREP Act as related to H1N1 requires the “direct physical” administration of a countermeasure and that the PREP Act does not apply to claims involving omission, non-use, or failure to act.

16. The Declaration defines “covered countermeasures” against COVID-19 as “any antiviral, any other drug, any biologic, any diagnostic, [or] any other device . . . used to treat, diagnose, cure, prevent, or mitigate COVID-19.” *Id.* at 15202. The PREP Act further includes in their definition of “covered countermeasure” any drug, biological product or device authorized for emergency use by the Federal Food, Drug, and Cosmetic Act (FDCA), and any respiratory protective device approved by the National Institute for Occupational Safety and Health (NIOSH). 42 U.S.C. § 247d-6d(i)(1).²

17. The Fourth Amendment to the Declaration issued December 3, 2020, incorporated by reference all Advisory Opinions into the Declaration itself, emphasizing that the Declaration and the PREP Act should be interpreted in accordance with those Advisory Opinions. 85 Fed. Reg. 79190, at 79192. The Fourth Amendment further clarified that immunity under the PREP Act from

² The Office of the Secretary specifically invoked immunity related to respiratory devices approved by NIOSH as covered countermeasures for a period from March 27, 2020, until October 1, 2024. 85 Fed. Reg. 21012.

both suit and liability may extend to situations of non-use or non-administration of covered countermeasures. 85 Fed. Reg. at 79191 and 79197.

18. Lastly, the Fourth Amendment to the Declaration recognizes that cases falling under the scope of the PREP Act present a substantial federal question within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mfg.*, 545 U.S. 308 (2005), and that there is a substantial federal legal and policy interest in a uniform interpretation of the PREP Act as it pertains to the unprecedented COVID-19 global pandemic. 85 Fed. Reg. at 79194, 79197.

19. Following the March 10, 2020 Declaration, HHS has continued to reinforce the PREP Act's complete preemption in its Advisory Opinions and Amendments to the Declaration. To date, the Declaration has been amended eight (8) times, four (4) of which have been under the Biden Administration, further confirming the expansive breadth of the Act and its preemptive effect.

20. In its April 17, 2020 Advisory Opinion, the Office of the Secretary reiterated: "PREP Act immunity must be read in light of the PREP Act's broad, express-preemption provision." (A copy of the April 17, 2020 Advisory Opinion, as Modified on May 19, 2020, is attached hereto as Exhibit "H"). On January 8, 2021, the Office of the Secretary issued Advisory Opinion 21-01, which plainly stated that the PREP Act is a complete preemption statute:

The *sine qua non* of a statute that completely preempts is that it establishes either a federal cause of action, administrative or judicial, as the only viable claim or vests exclusive jurisdiction in a federal court. The PREP Act does both.

(A copy of the January 8, 2021 Advisory Opinion is attached hereto as Exhibit "I").

21. Moreover, the Fifth Amendment to the Declaration issued on February 2, 2021, reiterated that "[t]he plain language of the PREP Act makes clear that there is a complete preemption of state law." Fifth Amendment to the Declaration Under the Public Readiness and

Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 86 Fed. Reg. 7872, 7874 (Feb. 2, 2021).

22. In the instant matter, Removing Defendant, as a licensed long term care facility, is a “covered person” as defined by the PREP Act.

23. At the time of the allegations set forth in the Complaint, Removing Defendant was acting as a “program planner” that was responsible for developing, administering and supervising countermeasure policies and procedures at Laurel Brook in an effort to mitigate the transmission of COVID-19, including those related to COVID infection control, use of personal protective equipment (PPE), and visitor restrictions.

24. Removing Defendant was also acting as a “qualified person” during the relevant time period, as they were a long term care facility licensed by the State of New Jersey Department of Health, authorized to perform screenings and evaluations of residents and administer the use of PPE and other countermeasures to mitigate the transmission of COVID-19.

25. Furthermore, Plaintiffs’ broad allegations against Removing Defendant – that she was allowed to contract COVID-19 – by necessity relate to COVID countermeasures employed by Laurel Brook, including the use and administration of PPE, COVID testing, screening procedures and other medical devices. Exhibit “A” at ¶ 34, 50(f). As such, Plaintiffs’ claims relating to Removing Defendant’s alleged actions and any conscious inactions relate to the use and administration of “covered countermeasures” and fall within the purview of the PREP Act.

26. Because Plaintiffs’ Complaint invokes the PREP Act, Congress provided an exclusive remedy for the substance of the allegations and relief sought in the Complaint and Federal law completely pre-empts state law for purposes of federal question jurisdiction. *See*

Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C. §§ 247d-6d, 247d-6e (2020).

27. Moreover, the PREP Act expresses its clear intention to preempt state law claims. Under 42 U.S.C. § 247d-6d(b)(8), state law that “is different from, or in conflict with, any requirement applicable [for immunity]” is expressly preempted. *See also Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58 (1987) (holding that a “clearly manifested intent of Congress” for complete preemption of a statute “is so powerful as to displace any state cause of action”).

28. The issue of whether federal question jurisdiction exists when a Complaint asserts a claim in state law is addressed in *Beneficial Nat. Bank v. Anderson*, 539 U.S. 1 (2003). The Court explained:

[A] state claim may be removed to federal court ... when a federal statute wholly displaces the state-law cause of action through **complete pre-emption**. When the federal statute completely pre-empts the state-law cause of action, a claim which comes within the scope of that cause of action, even if pleaded in terms of state law, is in reality based on federal law. In the two categories of cases where this Court has found complete pre-emption ... the federal statutes at issue **provided the exclusive cause of action** for the claim asserted and also **set forth procedures and remedies governing that cause of action**.

Id. at 8 (emphasis supplied; internal citations and footnotes omitted).

29. In *Beneficial*, the plaintiff brought an action for usury under state law, which was preempted by the usury provisions of the National Bank Act (12 U.S.C. §§ 85 and 86). The Court held that the usury provisions under §§ 85 and 86 collectively “supersede both the substantive and the remedial provisions of state usury laws and create a federal remedy for overcharges that is exclusive.” *Beneficial Nat. Bank, supra*, at 11. Therefore, the court held that federal question diversity was proper under the “complete preemption” doctrine.

30. Moreover, Circuit Courts and District Courts have subsequently found “complete preemption” where a federal statute expressly preempts state law and creates an exclusive federal

remedy for preempted state claims. *See, e.g., In re WTC Disaster Site*, 414 F.3d 352, 380 (2d Cir. 2005); *Spear Marketing, Inc. v. Bancorp South Bank*, 791 F.3d 586 (5th Cir. 2015); *Nott v. Aetna U.S. Healthcare, Inc.*, 303 F.Supp.2d 565 (E.D. Pa. 2004).

31. For example, in *Parker v. St. Lawrence Co. Pub. Health Dept.*, 102 A.D. 3d 140, 954 N.Y.S.2d at 262 (2012), the court held the more narrow H1N1 Declaration issued pursuant to the PREP Act warranted an exclusive federal forum and further held that state courts have no jurisdiction to hear claims arising out, or concerning, a declaration issued pursuant to the PREP Act.

32. Moreover, in *Garcia v. Welltower OpCo Group*, the Court held that the PREP Act provides for complete preemption in accordance with Advisory Opinion 21-01, and that “allegations of use and misuse of PPE and the infection control measures directly relate to covered countermeasures within the meaning of the PREP Act.” *Garcia v. Welltower OpCo Group*, 2021 WL 492581, at *7, *21 (C.D. Cal. Feb. 10, 2021).

33. In *Rachal v. Natchitoches Nursing & Rehabilitation Center, LLC*, the Court held that the PREP Act is a complete preemption statute, and that it “exclusively encompasses claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.” *Rachal v. Natchitoches Nursing & Rehabilitation Center, LLC*, No. 1:21-cv-334 at n.3 (W.D. La. Apr. 30, 2021) (attached hereto as Exhibit “J.”) *See also Reilly v. Delta Healthcare II, LLC*, No. 8:21-cv-1013-JSM-JSS (M.D. Fla June 7, 2021); *Branch v. Lilac Holdings, LLC*, No. 21-cv-00605-BAS-MDD (S.D. Cal. June 16, 2021) (conceding applicability of PREP Act granting defendants’ motion to dismiss based on immunities within the Act).

34. Congress has clearly manifested the intent to preempt state law with respect to claims that invoke PREP Act immunity and to create an exclusive federal remedy for such preempted claims, thereby “completely preempting” state law for purposes of federal question jurisdiction.

35. Here, Removing Defendant asserts that Plaintiffs’ COVID-19 tort claims are completely preempted by the PREP Act sections found at 42 U.S.C. §§ 247d-6d and 247d-6e. Under 42 U.S.C. § 247d-6d(a). A “covered person” is afforded broad immunity for all “claims for loss arising out of, relating to, or resulting from” the “administration” or “use” of a “covered countermeasure” as those terms are defined by that section, provided the Secretary of the Department of Health and Human Services (HHS) issues a declaration to that effect. As explained above, on its face, the allegations contained in the Complaint reflect that Removing Defendant is a “covered person” involved in a “recommended activity” involving the administration of a “covered countermeasure” and therefore presents a Federal Question under the Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C. §§ 247d-6d, 247d-6e (2020).

36. Therefore, Plaintiffs’ Complaint invokes a federal question for which the governing federal law “completely preempts” Plaintiffs’ state law COVID-19 claim, and removal is proper under 28 U.S.C. § 1441(a).

B. Removal Under the Federal Officer Statute, 28 U.S.C. § 1442(a)(1)

37. Under 28 U.S.C. § 1442(a)(1), removal is proper when a defendant is sued for actions undertaken at the direction of a federal officer.

38. The right of removal under the federal officer statute is “absolute . . . regardless of whether the suit could originally have been brought in a federal forum.” *Willingham v. Morgan*, 395 U.S. 402, 406 (1969) (emphasis added).

39. Furthermore, removal under § 1442 should be “broadly construed in favor of a federal forum.” *In re Commonwealth’s Motion to Appoint Counsel Against or Directed to Defender Ass’n of Philadelphia*, 790 F.3d 457, 466-67 (3d Cir. 2015) (internal quotation marks omitted) (quoting *Sun Buick, Inc. v. Saab Cars USA, Inc.*, 26 F.3d 1259, 1262 (3d Cir. 1994)).

40. Federal officer removal is proper if a defendant establishes that (1) it is a “person” within the meaning of the statute; (2) the claims are based upon the defendant’s conduct “acting under” the United States, its agencies, or its officers; (3) the claims against it are “for, or relating to” an act under color of federal office; and (4) defendant raises a colorable federal defense to the claims. *Id.* at 467 (citing *Ruppel v. CBS Corp.*, 701 F.3d 1176, 1180-81 (7th Cir. 2012)).

41. For the reasons set forth below, Removing Defendant satisfies all requirements of 28 U.S.C. § 1442(a)(1), such that removal is proper.

A. Removing Defendant is a “Person” within the Meaning of the Federal Officer Removal Statute

42. As a preliminary matter, Removing Defendant, a Limited Liability Company, is unquestionably a “person” under the federal officer statute. *See* 1 U.S.C. § 1 (“[T]he word[] “person” . . . include[s] corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals.”)

2. Removing Defendant “Acted Under” the Direction of a Federal Officer

43. The meaning of “acting under” should be “liberally construed,” and involves “effort to *assist* or to help *carry out*, the duties or tasks of the federal superior.” *Watson v. Phillip Morris Companies, Inc.*, 551 U.S. 142, 142, 152 (2007) (emphasis in original)

44. At the outset of the pandemic in March 2020, the federal government identified medical and healthcare services as essential to the “critical infrastructure industry,” and those providers had a “special responsibility” to continue operations and ensure implementation of

federal, state and local mandates and directives in the interest of public safety and delivery of critical infrastructure services.³

45. Other United States District Courts have recognized that this designation as “critical infrastructure” during the pandemic is sufficient to satisfy the requirement that an entity was “acting under” the direction of federal officials for the purposes of removal. *See Wazelle v. Tyson Foods, Inc.*, 2021 WL 2637335 at *5 (N.D. Tex. Jun. 25, 2021); *Fields v. Brown*, 2021 WL 510620 at *3 (E.D. Tex. Feb. 11, 2021).

46. Moreover, federal and state agencies including the Centers for Disease Control (CDC), Centers for Medicare & Medicaid Services (CMS), and the State of New Jersey Department of Health have issued various evolving advisories, directives, guidance and mandates to long term care facilities such as Removing Defendant regarding their response to the pandemic, including restricting visitors, canceling communal dining, canceling communal activities, screening residents and staff for symptoms, use of personal protective equipment (PPE) and infection control protocols to mitigate the spread of the virus. Additionally, CMS incorporated some of these mandates into new federal regulations, subjecting long term care facilities such as Removing Defendant to fines and penalties in instances of noncompliance. *See generally* 42 CFR § 483.80(g) (requiring weekly reporting to the CDC of PPE levels, hand hygiene and ventilator capacity, staffing, and cases among residents and staff); 42 CFR § 483.80(h) (requiring COVID-19 testing and reporting of the same to the CDC per Department of Health and Human Services).

³ See Memorandum on Identification of Essential Critical Infrastructure Workers During COVID-19 Response, CISA, <https://www.cisa.gov/sites/default/files/publications/CISA-Guidance-on-Essential-Critical-Infrastructure-Workers-1-20-508c.pdf> (last visited Sept. 3, 2021).

47. The countermeasures against COVID-19 implemented at Laurel Brook were based upon these federal mandates and guidelines. (*See* the Declaration of Valerie Lowman, former Director of Nursing at Laurel Brook, attached hereto as Exhibit “K”).

48. As such, Laurel Brook was acting at the direction of the federal government to implement procedures and protocols within the facility to prevent and contain the spread of COVID-19 and to provide necessary medical care and treatment to its residents, such as Tarar Cassel, in furtherance of the tasks and goals of the federal government and its various agencies. Therefore, the second element of federal officer removal is satisfied.

3. Plaintiffs’ Claims “Relate to” an Act Under the Direction of a Federal Officer

49. To meet the third requirement of the federal officer removal statute, there must be a “connection or association between the act in question and the federal office.” *In re Commonwealth’s Motion, supra*, 790 F.3d at 471 (internal quotation marks omitted); *see also Latiolais v. Huntington Ingalls, Inc.*, 951 F3d 286, 292 (5th Cir. 2020) (“Congress broadened federal officer removal actions, not just *causally* connected, but alternatively *connected* or *associated*, which acts under color of federal office.” [emphasis in original]).

50. However, a direct causal nexus between the act and the federal office need not exist. *Wazelle, supra*, 2021 WL 2637335 at *5.

51. Due to the interrelation between Removing Defendant’s response to the COVID-19 pandemic and the role of the federal government in the same, as explained *supra*, Plaintiffs’ claims directly relate to actions taken under the direction of a federal officer.

52. As previously explained, Plaintiffs claim that Laurel Brook negligently allowed Tarar Cassel to contract COVID-19 while at the facility. Exhibit “A” at ¶ 50(f).

53. Such a broad allegation implicates Laurel Brook's response to the COVID-19 pandemic, which can include any number of countermeasures such as use and allocation of PPE, infection control protocols, symptom screening, diagnostics and testing. As previously explained, said policies and protocols were implemented in direct response to directives from the federal government, including the CDC and CMS.

54. Therefore, Plaintiffs' claims as to Removing Defendant undoubtedly relate to Removing Defendant's actions under the direction of the federal government.

4. Removing Defendant Raises a Colorable Federal Defense to Plaintiffs' Claims

55. Federal officer removal will be allowed if "it appears that a Federal question or a claim to a Federal right is raised in the case." *In re Commonwealth's Motion*, 790 F.3d at 472-73 (quoting *Mesa v. California*, 489 U.S. 121, 126-27 (1989)).

56. A defendant "need not win" a case before qualifying for federal officer removal, as the purpose of the statute is "to have the validity of the defense of official immunity tried in a federal court." *Willingham, supra*, 395 U.S. at 407.

57. Here, Removing Defendant's colorable defense to Plaintiffs' claims is its immunity under the PREP Act, as well as the Act's complete preemption of Plaintiffs' claims, as more fully outlined *supra* and incorporated as if fully stated herein. As such, all elements of federal officer removal are satisfied, and removal pursuant to 28 U.S.C. § 1442(a)(1) is proper at this time.

WHEREFORE, Defendant, Laurel Brook Rehabilitation & Healthcare Center, respectfully request that the civil action number MID-L-4591-21 from the Superior Court of New Jersey, Middlesex County, Law Division, to the United States District Court for the District of New Jersey, Trenton Vicinage, pursuant to 28 U.S.C. § 1441(a), § 1442(a)(1).

BURNS WHITE LLC

By: /s/ William J. Mundy
William J. Mundy, Esquire
I.D. No. 035981989
Brian D. Pagano, Esquire
I.D. No. 016812007
457 Haddonfield Road, Suite 510
Cherry Hill, NJ 08002
(856) 382-6006 / Fax (856) 382-6007
Attorneys for Defendant,
Laurel Brook Rehabilitation & Healthcare
Center

Dated: September 7, 2021

CERTIFICATE OF SERVICE

The undersigned does hereby certify that on September 7, 2021, the within **NOTICE OF REMOVAL** was filed electronically with the United States District Court for the District of New Jersey, Trenton Vicinage, and to be served electronically upon the following:

Theodore C. Levy, Esquire
Fine and Staud, LLC
1333 Race Street
Philadelphia, PA 19107
Attorney for Plaintiffs

/s/ William J. Mundy
William J. Mundy, Esquire

Exhibit A

SUMMONS

Attorney(s) Theodore C. Levy, Esquire

Office Address 1333 Race Street

Town, State, Zip Code Philadelphia, PA 19107

Telephone Number (215) 665-0100

Attorney(s) for Plaintiff Patricia White and Tarar Cassel

Patricia White, individually and as guardian of Tarar Cassel
and Tarar Cassel

Plaintiff(s)

Vs.

Community Options, Inc., Virtua Willingboro Hospital,

Laurel Brook Rehabilitation & Healthcare Center, et al


Defendant(s)

From The State of New Jersey To The Defendant(s) Named Above:

The plaintiff, named above, has filed a lawsuit against you in the Superior Court of New Jersey. The complaint attached to this summons states the basis for this lawsuit. If you dispute this complaint, you or your attorney must file a written answer or motion and proof of service with the deputy clerk of the Superior Court in the county listed above within 35 days from the date you received this summons, not counting the date you received it. (A directory of the addresses of each deputy clerk of the Superior Court is available in the Civil Division Management Office in the county listed above and online at http://www.judiciary.state.nj.us/prose/10153_deptyclerklawref.pdf.) If the complaint is one in foreclosure, then you must file your written answer or motion and proof of service with the Clerk of the Superior Court, Hughes Justice Complex, P.O. Box 971, Trenton, NJ 08625-0971. A filing fee payable to the Treasurer, State of New Jersey and a completed Case Information Statement (available from the deputy clerk of the Superior Court) must accompany your answer or motion when it is filed. You must also send a copy of your answer or motion to plaintiff's attorney whose name and address appear above, or to plaintiff, if no attorney is named above. A telephone call will not protect your rights; you must file and serve a written answer or motion (with fee of \$135.00 and completed Case Information Statement) if you want the court to hear your defense.

If you do not file and serve a written answer or motion within 35 days, the court may enter a judgment against you for the relief plaintiff demands, plus interest and costs of suit. If judgment is entered against you, the Sheriff may seize your money, wages or property to pay all or part of the judgment.

If you cannot afford an attorney, you may call the Legal Services office in the county where you live or the Legal Services of New Jersey Statewide Hotline at 1-888-LSNJ-LAW (1-888-576-5529). If you do not have an attorney and are not eligible for free legal assistance, you may obtain a referral to an attorney by calling one of the Lawyer Referral Services. A directory with contact information for local Legal Services Offices and Lawyer Referral Services is available in the Civil Division Management Office in the county listed above and online at http://www.judiciary.state.nj.us/prose/10153_deptyclerklawref.pdf.


Clerk of the Superior Court

DATED: 08/05/2021

Name of Defendant to Be Served: Laurel Brook Rehabilitation & Healthcare

Address of Defendant to Be Served: 3718 Church Road, Mt. Laurel, NJ 08054

FINE AND STAUD, LLC

BY: Theodore C. Levy, Esquire

Attorney ID No: 036002011

1333 Race Street

Philadelphia, PA 19107-1585

Tel: (215) 665-0100

Fax: (267) 710-7004

Attorney for Plaintiffs, Patricia White, individually, and as guardian of Tarar Cassel and Tarar Cassel

PATRICIA WHITE, individually and as	:	SUPERIOR COURT OF NEW JERSEY
guardian of TARAR CASSEL	:	LAW DIVISION
534 S. 51 st Street	:	
Philadelphia, PA 19143	:	MIDDLESEX COUNTY
&	:	
TARAR CASSEL	:	DOCKET NUMBER
14 Overington Avenue	:	
Marlton, NJ 08053	:	Civil Action
	:	
V.	:	
	:	
COMMUNITY OPTIONS, INC.	:	
16 Farber Road	:	COMPLAINT AND
Princeton, NJ 08450	:	DEMAND FOR JURY TRIAL
&	:	
VIRTUA WILLINGBORO HOSPITAL	:	
218A Sunset Road	:	
Willingboro, NJ 08046	:	
&	:	
LAUREL BROOK REHABILITATION &	:	
HEALTHCARE CENTER	:	
3718 Church Road	:	
Mt. Laurel, NJ 08054	:	
&	:	
POWERBACK REHABILITATION -	:	
PISCATAWAY	:	
10 Sterling Drive	:	
Piscataway, NJ 08854	:	
&	:	
JOHN DOE #1-10(fictitious) and	:	
ABC CORPORATON #1-10 (fictitious)	:	
(representing previously unidentified	:	
physicians and medical providers)	:	

Plaintiffs, Patricia White, an adult, individually and as the mother and guardian of Tarar Cassel, and Tarar Cassel, an adult, residing at the above stated addresses, by and through their attorney, Theodore C. Levy, Esquire, state:

IDENTIFICATION OF THE PARTIES

1. Plaintiff, Patricia White, is an adult individual residing at the above stated address and is the mother and guardian of Tarar Cassel, who suffers from severe intellectual disabilities.

2. Plaintiff, Tarar Cassel, is an adult individual residing at the above stated address, who has severe intellectual disabilities and is unable to live independently or care for herself as a result.

3. Defendant, Community Options, Inc. (hereinafter referred to as "Community Options"), is a corporation, hospital, medical institution and facility, and/or other business entity that operates a business practice for physicians, nurses, and other medical staff at the above stated address.

4. At all times relevant hereto, Defendant, Community Options, held itself and its agents, servants, workers, representatives, physicians, nurses, staff, contractors, medical personnel, and employees out to be skillful and qualified to attend, care for, treat and render medical care and services to patients such as Plaintiff, Tarar Cassel.

5. Defendant, Virtua Willingboro Hospital (hereinafter referred to as "Virtua Willingboro"), is a corporation, hospital, medical institution and facility, and/or other business entity that operates a business practice for physicians, nurses, and other medical staff at the above stated address.

6. At all times relevant hereto, Defendant, Virtua Willingboro, held itself and its agents, servants, workers, representatives, physicians, nurses, staff, contractors, medical personnel, and employees out to be skillful and qualified to attend, care for, treat and render medical care and services to patients such as Plaintiff, Tarar Cassel.

7. Defendant, Laurel Brook Rehabilitation & Healthcare Center (hereinafter referred to as "Laurel Brook"), is a corporation, hospital, medical institution and facility, and/or other business entity that operates a business practice for physicians, nurses, and other medical staff at the above stated address.

8. At all times relevant hereto, Defendant, Laurel Brook, held itself and its agents, servants, workers, representatives, physicians, nurses, staff, contractors, medical personnel, and employees out to be skillful and qualified to attend, care for, treat and render medical care and services to patients such as Plaintiff, Tarar Cassel.

9. Defendant, PowerBack Rehabilitation – Piscataway (hereinafter referred to as “PowerBack”), is a corporation, hospital, medical institution and facility, and/or other business entity that operates a business practice for physicians, nurses, and other medical staff at the above stated address.

10. At all times relevant hereto, Defendant PowerBack, held itself and its agents, servants, workers, representatives, physicians, nurses, staff, contractors, medical personnel, and employees out to be skillful and qualified to attend, care for, treat and render medical care and services to patients such as Plaintiff, Tarar Cassel.

11. Defendants, John Doe #1-10, is an adult individual(s) who at all times material hereto, was a practicing physician, nurse, or other healthcare provider in the State of New Jersey, and was, an agent, ostensible agent, servant, representative, and/or employee of Defendants, Community Options, Virtua Willingboro, Laurel Brook, PowerBack and/or ABC Corporation 1-10 and who is being sued by Plaintiffs under a fictitious name, pursuant to R.4:26-4.

12. At all times mentioned herein and material hereto, Defendant, John Doe #1-10, represented himself/herself out to be a competent, skillful, and qualified healthcare provider, qualified to practice, attend, treat, and administer medical care and treatment upon and to patients such as Plaintiff, Tarar Cassel.

13. Defendant, ABC Corporation #1-10, is a corporation, hospital, medical institution and facility, and/or other business entity that operates a business practice for physicians, nurses, and other medical staff was involved in the medical care of Plaintiff, and is being sued by Plaintiff under a fictitious name, pursuant to R.4:26-4.

14. At all times relevant hereto, Defendant ABC Corporation #1-10, held itself and its agents, servants, workers, representatives, physicians, nurses, staff, contractors, medical personnel, and employees out to be skillful and qualified to attend, care for, treat and render medical care and services to patients such as Plaintiff, Tarar Cassel.

OPERATIVE FACTS

15. Plaintiff, Tarar Cassel is an intellectually disabled woman who has severe autism and retardation and is non-verbal and unable to care for herself or live independently, and therefore, her mother, Patricia White, has been appointed as her guardian.

16. Prior to July 20, 2020, Tarar Cassel was residing at Community Options housing for the disabled, located at 205A Harwood Court, Mt. Laurel, NJ 08054.

17. On July 20, 2020, Tarar Cassel was taken to Virtua Express Urgent Care Moorestown due to skin breakdown and ruptured blister of the right 5th toe.

18. Upon discharge from Virtua Express Urgent Care Moorestown, Tarar Cassel's caregiver was instructed to take Tarar Cassel to a podiatrist as soon as possible.

19. On July 22, 2020, Tarar Cassel was taken by a caregiver to see podiatrist Dr. Rinsa Mathews, where she was diagnosed with an ulcer on her 5th right toe. It was further noted that the ulcer was not new and was suspected of forming several weeks prior. She was further instructed to undergo x-rays and follow up.

20. On July 28, 2020, Tarar Cassel underwent bloodwork and x-rays of her right toe.

21. On August 5, 2020, Tarar Cassel returned to Dr. Rinsa Mathews where she was again diagnosed her with an ulcer on her right 5th toe. Furthermore, Dr. Mathews informed Tarar Cassel's caregiver that the x-ray was positive for dislocation of the distal phalanx of the right 5th toe. Dr. Mathews discharged Tarar Cassel and instructed her caregiver to bring Ms. Cassel back for a follow up.

22. On August 10, 2020, Tarar Cassel was returned to Dr. Rinsa Mathews to be evaluated. At that visit, Tarar Cassel's caregiver noted that she had re-injured the toe and suspected that Tarar had been picking at the toe and/or rubbing the toe. Dr. Mathews found that the toe was in a worsened condition with a wound in the 4th interspace and a serious infection, with a visible tendon. Tarar was screaming in pain during this visit.

23. As a direct result of the severe condition of Tarar Cassel's 5th right toe, Dr. Mathews recommended that she go directly to the emergency room at Virtua Willingboro Hospital.

24. On August 10, 2020, after leaving Dr. Mathews' office, Ms. Cassel was taken by her caregiver to Virtua Willingboro and was admitted due to the severe infection of her toe.

25. The injury to Tarar Cassel's 5th right toe was directly and proximately caused by the failure of Community Options to properly supervise her, which would have prevented said injury.

26. Furthermore, Tarar Cassel's injury was not noted until weeks or months after it had occurred, allowing it to get infected.

27. Even after the infection was discovered at Community Options, Tarar Cassel was not properly cared for, as they allowed Tarar to pick at her infection which made the condition so severe that it required amputation.

28. Tarar Cassel remained at Virtua Willingboro from August 10, 2020 to August 18, 2020 and during this visit had her 5th right toe amputated due to the severity of the infection.

29. On August 18, 2020, Tarar Cassel was discharged from Virtua Willingboro Hospital and was sent to Laurel Brook Rehabilitation where she stayed until September 8, 2020.

30. On September 8, 2020, Tarar Cassel returned home to Community Options.

31. On September 11, 2020, Tarar Cassel tested positive for Covid-19 and was highly symptomatic.

32. As a result of a symptomatic Covid-19 infection, Ms. Cassel was taken to Virtua Hospital Willingboro on September 11, 2020.

33. Tarar Cassel remained hospitalized for Covid-19 at Virtua Willingboro from September 11, 2020 to September 18, 2020.

34. Due to the fact that Plaintiff became symptomatic and tested positive for Covid-19 on September 11, 2020, she contracted Covid-19 at either Laurel Brook or Community Options because those were the only places she had been in the previous fourteen (14) days)

35. On September 18, 2020, Tarar Cassel was discharged and returned home to Community Options.

36. On September 19, 2020, Tarar Cassel was readmitted to Virtua Willingboro due to erratic behavior and difficulty walking noted by Community Options.

37. From September 19, 2020 to September 25, 2020, Tarar Cassel was admitted to Virtua Willingboro. During this time, it was noted that she was unable to walk as she was not able to bear weight on her leg. It was noted in the records that she would stand with her leg semi-flexed and would not step.

38. On September 20, 2020, during her inpatient stay at Virtua Willingboro, Ms. Cassel was noted to have a right knee ulcer and underwent an x-ray of said knee due to suspected trauma, which was a negative study.

39. On September 25, 2020, Tarar Cassel was discharged from Virtua Willingboro and was sent to PowerBack Rehabilitation – Piscataway, because she still could not walk on her right leg and therefore was not able to be in her group home at Community Options.

40. From September 25, 2020 to November 11, 2020, Tarar Cassel was admitted inpatient at PowerBack and the PowerBack records note that she was having great difficulty walking.

41. On November 11, 2020, Tarar Cassel was sent to a different Community Options location that would be better able to accommodate her difficulty walking, located at 6407 Normandy Drive, Mt. Laurel, NJ 08054.

42. On November 17, 2020, Tarar Cassel was taken to Virtua Memorial Hospital of Burlington and was admitted. The reason for her admission was that there was substantial swelling around her right ankle and that she was badly limping.

43. On November 18, 2020, Tarar Cassel had an x-ray performed that found subacute fractures to both the tibia and fibula that were in the process of healing. The fracture of the tibia was especially bad and was noted to be a comminuted distal tibia fracture deformity with a visible fracture line and evidence of healing.

44. The Virtua Burlington records indicate that her doctors believed that these fractures occurred approximately three (3) months prior. Despite the fact that the fractures had occurred weeks or months prior, her treating providers at Community Options, Virtua Willingboro, Laurel Brook, and PowerBack did not mention any trauma or any suspected fractures.

45. There were further notations in the Virtua Burlington records that the doctors believed that abuse may be going on and stated that this would be referred to Adult Protective Services.

46. In the time 1-4 months prior to the diagnosis of the subacute healing fractures to the tibia and fibula, Tarar Cassel had been inpatient at Community Options, Virtua Willingboro, Laurel Brook, and PowerBack. The records are replete with references that Ms. Cassel was having trouble walking, which is very likely due to the tibia and fibula fractures.

47. During the time the fracture would have occurred, Tarar Cassel was under the care of Community Options, Virtua Willingboro, Laurel Brook, and/or PowerBack. Not one of these entities took proper care of her, allowing her to suffer serious injuries and failing to do proper diagnostic studies that would have determined that she suffered multiple fractures.

FIRST COUNT
MEDICAL MALPRACTICE / NEGLIGENCE
PLAINTIFFS, PATRICIA WHITE, INDIVIDUALLY AND AS PARENT AND GUARDIAN OF
TARAR CASSEL & TARAR CASSEL V. DEFENDANTS, COMMUNITY OPTIONS, INC.,
VIRTUA WILLINGBORO HOSPITAL, LAUREL BROOK REHABILITATION &
HEALTHCARE CENTER, POWERBACK – PISCATAWAY, JOHN DOE INDIVIDUALS #1-10,
AND ABC CORPORATIONS #1-10

48. Plaintiffs repeat each and every allegation contained in this Complaint as though set forth at length herein.

49. Defendants, Community Options, Inc., Virtua Willingboro Hospital, Laurel Brook Rehabilitation & Healthcare Center, PowerBack Rehabilitation – Piscataway, John Doe Individuals #1-10, and ABC Corporations #1-10 are liable for the negligence of the doctors, nurses, and other healthcare providers who participated in Plaintiff's care, under the doctrines of respondeat superior, agency, apparent agency, and otherwise.

50. Defendants, Community Options, Inc., Virtua Willingboro Hospital, Laurel Brook Rehabilitation & Healthcare Center, PowerBack Rehabilitation – Piscataway, John Doe Individuals #1-10, and ABC Corporations #1-10's negligence consisted of but is not limited to the following:

- a. Allowing Plaintiff to suffer a dislocation of the distal phalanx of the right 5th toe and an open wound on said toe;
- b. Allowing the wound on Plaintiff's right 5th toe to become infected;
- c. Failing to promptly discover that Plaintiff had a wound on her right 5th toe that was infected;
- d. Failing to properly treat the infection to Plaintiff's right 5th toe after it was discovered;
- e. Allowing Plaintiff's right 5th toe to get into such bad condition that it had to be amputated;
- f. Allowing Plaintiff to contract Covid-19 while under the care of Defendants;
- g. Failing to properly supervise Plaintiff so that she would not fall and suffer injuries;
- h. Allowing Plaintiff to fall and suffer injuries;

- i. Failing to properly diagnose Plaintiff with a fracture to her tibia and fibula after she suffered these injuries;
- j. Delaying treatment for Plaintiff's fractured tibia and fibula due to the delayed diagnosis; and
- k. Providing medical care and treatment to Plaintiff that was below the standard of care in the community, thereby increasing the risk of harm to Plaintiff's well-being.

51. As a result of Community Options, Inc., Virtua Willingboro Hospital, Laurel Brook Rehabilitation & Healthcare Center, PowerBack Rehabilitation – Piscataway, John Doe Individuals #1-10, and ABC Corporations #1-10's breach of the standard of care, Plaintiff, Tarar Cassel suffered a dislocation of the 5th distal phalanx, a blister on the right 5th toe that ruptured, an infection to the right 5th toe that became so severe that it required amputation, Covid-19 with severe enough symptoms to require hospitalization, fractured right tibia, fractured right fibula, contusions and an open wound to Plaintiff's right knee, severe lower extremity pain, severe difficulty with ambulation, increased anxiety, increased depression, and aggravation of preexisting conditions, if any, all or some of which are or may be permanent. Plaintiff also makes claim for such injuries, damages and consequences of which she has no present knowledge.

52. As a further result of this failure to diagnose, Plaintiff, Tarar Cassel, has been or will be obliged to receive and undergo medical attention and care and to expend various sums of money and/or to incur various expenses for the injuries she has suffered and she may be obliged to continue to expend such sums or incur such expenditures for an indefinite time in the future.

53. As a further result of this failure to diagnose, Plaintiff, Tarar Cassel, has or may suffer a severe loss of her earnings and of her earning capacity and power.

54. As a direct and reasonable result of this failure to diagnose, Plaintiff, Tarar Cassel, has or may hereafter incur financial expenses or losses which do or may exceed amounts she may otherwise be entitled to receive.

55. As a further result of this failure to diagnose, and by reason of the injuries as aforesaid, Plaintiff, Tarar Cassel, has suffered and in the future may continue to suffer great pain and agony, mental anguish and humiliation and has been, and may in the future, be hindered from attending to her daily duties, function and occupation, to her great detriment and loss.

56. During the course of treating the Plaintiff in connection with the medical services provided to her, Defendants Community Options, Inc., Virtua Willingboro Hospital, Laurel Brook Rehabilitation & Healthcare Center, PowerBack Rehabilitation – Piscataway, John Doe Individuals #1-10, and ABC Corporations #1-10 negligently and carelessly failed to exercise reasonable the degree of skill, diligence, and care commonly exercised by other doctors and practice groups in like circumstances giving due regard to the existing state of knowledge in medicine, failed to properly treat the Plaintiff, failed to timely diagnose Plaintiff's condition, failed to properly treat his condition, and otherwise failed to act as a prudent, skillful, and careful healthcare provider or practice group in connection with the services provided to the Plaintiff, resulting in injuries to the Plaintiff.

WHEREFORE, Plaintiffs, Patricia White, individually and as parent and guardian of Tarar Cassel and Tarar Cassel, demand judgment against the Defendants, Community Options, Inc., Virtua Willingboro Hospital, Laurel Brook Rehabilitation & Healthcare Center, PowerBack Rehabilitation – Piscataway, John Doe Individuals #1-10, and ABC Corporations #1-10 individually, jointly, severally, and/or vicariously, for damages, interest, punitive damages, and costs of suit.

DEMAND FOR JURY

PLEASE TAKE NOTICE that the Plaintiffs hereby demand a jury trial as to all of the within issues.

**DEMAND FOR COMPLIANCE WITH
NJ COURT RULES 1:5-1(a) AND 4:17-4(c)**

TAKE NOTICE the undersigned attorney, counsel for Plaintiff, hereby demands, pursuant to the provisions of Rules 1:15-1(a) and 4:17-4(a), that each party serving pleadings or interrogatories and receiving responses thereto shall serve copies of all such pleadings, interrogatories and responses thereto upon the undersigned and further, TAKE NOTICE that this is a continuing demand.

**DEMAND FOR ANSWERS TO INTERROGATORIES
TO BE INCLUDED IN ALL COMPLAINTS**

Pursuant to Rule 4:17-1(b), Plaintiff hereby demand that Defendants provide answers to the uniform interrogatories set forth in Form C and C(3) of Appendix II of the Rules Governing the Courts of the State of New Jersey.

DEMAND FOR DISCOVERY OF INSURANCE COVERAGE

Pursuant to R. 4:10-2(b), demand is hereby made that you disclose to the undersigned whether there are any insurance agreements or policies under which any person or entity carrying on an insurance business may be liable to satisfy part or all of a judgment which may be entered in this action or to indemnify or reimburse for payments made to satisfy the judgment.

If so, provide to the undersigned a copy of each policy or agreement, or in the alternative state, under oath or certification; (a) policy number; (b) name and address of insurer; (c) inception and expiration dates; (d) names and addresses of all persons/entities covered; (e) personal injury limits; (f) property damage limits; (g) medical payment limits.

DEMAND FOR PRODUCTION OF ALL MEDICAL RECORDS

Pursuant to Rule 4:18-1, demand is hereby made that Defendants produce to Plaintiff's attorney the entire and complete medical records relating to any medical care provided by Defendants

to Plaintiff at any time. The demand shall be deemed to include any and all documents, including, but not limited to, memoranda, handwritten notes, office and hospital records, test results, diagnostic tests, actual x-rays, CAT scans, MRI films, tissue samples, slides, etc. This demand shall further include all documents sent by or at the request of Defendants to any insurance carrier or third party for payment of bills incurred for providing medical care to Plaintiff. All documents and other materials are to be produced to the office of Plaintiff's attorney within forty-five (45) days.

DEMAND FOR INSPECTION OF ORIGINAL RECORDS

Pursuant to Rule 4:18-1, demand is hereby made that the Defendants make available all original records described in the preceding demand for inspection within forty-five (45) days.

DEMAND FOR PRODUCTION OF TRANSCRIBED MEDICAL RECORDS

Pursuant to the New Jersey Administrative Code, demand is hereby made that the Defendants transcribe the original medical records described in the Demand for Production of Documents within thirty (30) days.

NOTICE OF NO OTHER ACTION

Pursuant to **Rule 4:5-1** the Plaintiff's Attorney hereby certifies to the best of his knowledge that there is no other action or arbitration pending in which the matter in controversy is the subject.

AFFIDAVIT OF MERIT

An Affidavit of Merit shall be timely filed pursuant to Rule 2A:53A-27.

DESIGNATION OF TRIAL COUNSEL

PLEASE TAKE NOTICE that Theodore C. Levy, Esquire, is hereby designated trial counsel on behalf of the law firm of Fine and Staud, LLC, Attorney for Plaintiff, Patricia White, individually and as guardian for Tarar Cassel, and Tarar Cassel.

CERTIFICATION

I, Theodore C. Levy, Esquire, of full age, hereby certify as follows:

1. The matter in controversy is not the subject of any other action pending in any Court or a pending Arbitration Proceeding;

2. There are no other known parties who should be joined in this action at this time;

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Respectfully submitted,

FINE AND STAUD, LLC

BY: Theodore C. Levy
THEODORE C. LEVY, ESQUIRE
Attorney for Plaintiffs

DATE: 8/3/21

AFFIDAVIT OF MERIT PURSUANT TO TARAR CASSEL

I, Catherine J. Brown, MSN, RN-BC, ONC, CRRN being of full age, duly sworn according to law hereby under oath:

1. I am a licensed Registered Nurse.
2. I am a Certified Medical Surgical Nurse, Certified Rehabilitation Nurse, and a Certified Orthopaedic Nurse.
3. I am duly admitted to practice Nursing in the Commonwealth of Massachusetts and Rhode Island.
4. Within five (5) years of the events at issue in this matter, I had clinical experience, provided consultation relating to clinical practice or taught nursing in the same specialty or a related field of health care as that of the health care providers discussed herein.
5. A copy of my current Curriculum Vitae is attached hereto.
6. I have no financial interest in the outcome of this case.
7. Pursuant to the request of Theodore C. Levy, attorney for the plaintiff Tarar Cassel and Patricia M. White, Legal Guardian and Mother, I have reviewed the medical records including, but not limited to:
 - a. Records from Dr. Rinsa Mathews, DPM
 - b. Virtua Urgent Care (09/30/18; 08/10/19; 12/16/19; 01/03/20; 01/13/20; 04/07/20; and 07/20/20)
 - c. New Jersey Individualized Service Plans (NJISP), Division of Developmental Disabilities (02/19/20; 10/26/20; and 11/10/20).
 - d. Community Options, Inc.- Special Needs Poole Trust Grantor Agreement
 - e. Virtua Lourdes Medical Center of Burlington County, Philadelphia, PA

- f. State of New Jersey office of public Defender, Division of Mental Health and Guardianship Advocacy, guardian appointment papers of Patricia Cassel White as guardian for Tarar Cassel.
 - g. Virtua Hospital Willingboro (09/11/20- 09/18/20; 09/19/20-09/25/20)
 - h. PowerBack Rehab (09/25/20-11/11/20)
 - i. Virtua Memorial Hospital of Burlington (11/17/20-11/30/20)
8. Based upon review of this case, there exists a reasonable probability that the care, skill, and knowledge exercised by the caretakers of Community Options Group Home, Virtua Willingboro, Laurel Brook Rehab, and PowerBack Rehab, fell outside the acceptable professional standards and treatment practices.
- (a) Community Options, the group home where Tarar Cassel resided, violated the standard of care by failing to timely and appropriately report to a physician new findings and complaints, including increasing, acute severe pain, failing to timely and appropriately perform complete physical examinations of Ms. Cassel and otherwise failing to timely and appropriately respond to Ms. Cassel's evolving infection leading to further toe dislocation, osteomyelitis, and toe amputation. As a result, this led to prolonged hospitalizations, the need for rehabilitation, the development of COVID 19, and finally discovery of a closed fracture of the tibia and fibula. In addition to these findings, Ms. Cassel sustained other injuries while under the care of Community Options. She went to urgent care after an open wound on her right knee (09/30/18); bursitis of an elbow joint (08/10/19); facial trauma and eye swelling after an unwitnessed fall from bed (12/16/19); dark purple bruises measuring 2 x 2 inches with pain upon palpation of her left outer thigh (01/02/20); traumatic hematoma of her forehead and contusion above her brow after a fall (01/13/20); and a laceration requiring three (3) sutures to her right

buttock (04/17/20). This is significant due to the fact that Virtua Memorial of Burlington (11/17/20-11/30/20) suggested the possibility of adult abuse and suspected that the fracture identified while under their care at Virtua Memorial of Burlington had occurred within the timeframe of three (3) months prior.

(b) After Ms. Cassel had her toe amputation at Virtua Willingboro Hospital (08/10/20-08/18/20), she was discharged to Laurel Brook rehab (08/18/20-09/08/20) for further rehabilitation. Once rehab was completed, she was discharged back to the group home from 09/08/20-09/11/20. She was readmitted back to Virtua Hospital from 09/11/20 to 09/19/20) where she tested positive and was treated for COVID 19 and pneumonia. She was discharged back to the group home from 09/18/20-09/19/20 and was noted that she was behaving erratically (i.e. combative; urinating and defecating on the floor; being very destructive) which was not her norm. Thus, she was sent back to Virtua Hospital Willingboro (09/19/20-09/25/20). Due to her inability to ambulate, bare weight, standing with her leg semi flexed and would not take a step, as well as increased WBC, tachycardia, and persistent infiltrate of her left lung, she was admitted for further treatment and work-up. On 09/20/20, Ms. Cassel had an x-ray of her right knee after she was noted to have an "ulcerated area on her right knee with minimal drainage." Her knee x-ray result was noted as "negative for fracture." However, the distal tibia and fibula fractures would not have been seen on an x-ray of the knee. Thus, further work-up was required to investigate the cause of her symptoms. Ms. Cassel was also ordered for a wound care consult by the wound ostomy nurse who attempted to evaluate the patient. However, per the 09/21/20 NP note, Ms. Cassel was "sleeping curled up on her side. RN declines need for assessment of right knee at this time." The wound nurse may have discovered something else going on with her leg had she been allowed to examine Ms.

Cassel. She was discharged and was admitted to PowerBack Rehab for rehab therapy due to “ambulatory dysfunction.”

(c) During her rehab stay at PowerBack, Ms. Cassel fell a total of six (6) times including the day of admission: 09/25/20; 09/29/20; 10/08/20; 10/28/20 x 2; and 11/01/20. In a note documented by the Nurse Practitioner on 09/25/20, the day of admission, she noted “recurrent fall- patient is a high risk for falls. Fall etiology is unclear as fall unwitnessed.” Ms. Cassel was often noted to be “sitting on the floor” in four out of the six documented falls and was also witnessed once “crawling on her hands and knees.” She was identified as a “high fall risk” upon admission and throughout her hospitalization, yet the nursing staff failed to provide and document other interventions they attempted (frequent checks, continuous hourly rounding, 1:1 continuous observation, placement near the nurses’ station) to keep her safe from falling. The nursing staff noted that “safety measures are in place and call bell [is] within reach,” yet documented that she “does not demonstrate how to use call bell” and her “decision making skills [are] severely impaired.” On 11/01/20, she was noted to have a “dry scab/patch of skin on her right knee.” Though noted in the record, further assessment of her leg was not done to evaluate other potential causes of “ambulatory dysfunction” or rule out other fractures or causes for the falls.

(d) Ms. Cassel was eventually discharged back to another group home with Community Options (11/11/20-11/17/20) until she was noted to have swelling in her ankle. She was transferred to Virtual Memorial of Burlington (11/17/20-11/30/20) where she presented with “foot injury and limping” She was noted to have a “closed fracture of the distal end of the right tibia.” An x-ray of her right ankle showed “healing subacute distal tibia and fibular fracture” on 11/18/20, despite “no reported history of fall or injury from the group

home.” There were notes stating “unclear circumstances leading to fracture. Old healing subacute distal tibia and fibula fracture [...] consult case management for evaluation by Adult Protective Services, 1:1 for safety [...] there is possible adult abuse.”

(e) The x-ray showed a “mildly displaced oblique fracture of the distal tibial shaft and approximately 6 mm of displacement and large amount of callous formation is seen indicating healing. Also seen is a nondisplaced oblique fracture of distal fibula with adjacent callous- healing subacute distal tibia & fibular fracture, distal tibial fracture deformity with visible fracture line and evidence of healing.” It was suspected that the fractures were “acute on chronic” and it was suspected that the fractures occurred approximately three (3) months prior. Thus, without an exact date of the fracture, the fracture could have occurred at Community Options, Virtua Willingboro, Laurel Brook Rehab, or PowerBack Rehab. These four specific facilities had the duty to assess, reassess, intervene and follow-up with patient’s presenting condition to ensure she received the care that she needed. As a nonverbal, developmentally delayed patient, with many co-existing comorbidities (i.e. hypothyroidism; bipolar disease; autism; seizure disorder, etc.) Ms. Cassel depended upon the nursing staff to appropriately care for her. She was unable to care and advocate for herself, yet the nursing staff failed to appropriately care for her and provide for her safety under their care.

9. I further attest that I do not annually devote more than 20% of my professional activities to activities that directly involve testimony in personal injury claims.
10. I have a right to amend my opinion once more medical records become available.
11. I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.



Catherine J. Brown, MSN, RN-BC, ONC, CRRN

Dated: 08/03/21

CATHERINE J. BROWN, MSN, RN-BC, ONC, CLNC, CRRN, LNCC
1715 PLYMOUTH STREET
BRIDGEWATER, MA 02324
Telephone: (508) 279-1886 · Cell (508) 942-1094 · Fax (508) 697-7160
Email: BrownLNC@comcast.net

NURSE LEADER:

EDUCATION:

LICENSURE: **MA** Registered Nurse 198438

RI Registered Nurse 58342

CERTIFICATIONS:

PROFESSIONAL EXPERIENCE:

- Assisted and directed acute medical management of patients including transfers to higher levels of care both internally & externally, patient cohorting, isolation, and testing of all patients with the National Guard, state & vendor labs, and own employees on multiple occasions.
- Developed urgent process for hiring staff from multiple agencies and successfully mitigated staffing crisis.
- Created emergency personal protective equipment (PPE) office, while providing education to all staff in absence of Nurse Educators, and overseeing appropriate management of entire process.
- Assisted with policies, procedures, guidelines, and plans related to potential Covid resurgence.
- Managed multiphase ligature mitigation project on five units including construction projects (safety screens, wiring, furniture), increased surveillance and monitoring of patients, and relocation of five entire units/6 moves.
- Participated in multiple Joint Commission (TJC), Department of Mental Health (DPH), Centers for Medicare Services (CMS). Disability Law Center (DLC) surveys and site visits.
- Directly supervise 170 employees/ 170+ FTEs in the Nursing department, including Nurse Managers, Nursing Supervisors, Nurse Educators, Registered Nurses, LPNs, Mental Health Workers, Unit Clerks, and Administrative Assistants.
- Ensure safe staffing levels based upon acuity of patients including 1:1 supervision and constant observation.
- Implement new policies and review existing policies to ensure safe nursing practice & excellent patient care based upon evidenced based care.
- Collaborate with Labor Relations and Human Resources regarding employee disciplinary processes.
- Collaborate with the leadership members of the MNA, AFSME, SEIU, and NAGE unions to ensure positive, and collaborative working relationships.
- Serve as a member of the Mock Joint Commission Survey Team for MA Department of Mental Health Hospitals.
- Provide direct patient care as needed and respond to behavioral codes, medical codes, and rapid responses.

(2016-2017)

LUBIN & MEYER, PC
Nurse Reviewer

Boston, MA

- Managed 30+ medical malpractice claim case load, not in suit (NIS) division.
- Reviewed plaintiff claims for potential medical malpractice, presented findings to attorney partners, consulted with clients and experts, and wrote reports.

(2014-2016)

SPAULDING REHABILITATION HOSPITAL CAPE COD (SCC) East Sandwich, MA
Director of Nursing

- As part of the Senior Leadership Team, managed 60 bed acute rehabilitation hospital.
- Specialties included: Orthopedics, Complex Medical, Neuro (including CVA, TBI, SCI) and post Cardiac surgery
- Achieved deficiency free Joint Commission Accreditation survey (2015) by supporting quality and patient safety initiatives.
- Partnered with DPH, Quality, and Risk Management to further investigate & resolve self-reported complaints.
- Achieved and maintained 99th percentile patient satisfaction scores.

- Transferred strategic initiatives into action through successful implementations.
- Provided education and oversight of technology conversions: Philips Telemetry, Pyxis to Omnicell, and Meditech to Epic.
- Responsibilities included twenty-four-hour hospital accountability, budgeting, personnel management, staff education, staffing & scheduling, and direct patient care as needed.
- Directly supervised 170 employees/ 100+ FTEs in the following departments: Nursing, Occupational Health/ Infection Control, Respiratory, Laboratory, Nursing Informatics, Social Work, and Staff Education.
- Active committee member for both SCC and Spaulding Rehabilitation Network (SRN.)
- Co-Chaired Joint Therapy & Nursing Practice Council, Professional Nurse Practice Council, and developed and Co-Chaired Rehab Aide/CNA Practice Council to empower Nurses, CNAs, and Therapists to positively impact patient care.
- Authored & updated policies/procedures to improve patient care and reflect evidenced based practice.

(2011-2014) JORDAN HOSPITAL/ BETH ISRAEL DEACONESS HOSPITAL, PLYMOUTH (MA)
Nursing Director, Med/Surg

- Managed 44 bed medical/surgical area and 15-32 bed overflow unit (census driven.) Areas consisted of general medical & surgical telemetry units, 5 bed adult medical short stay/telemetry observation unit, and 8 bed acute care of the elderly (ACE) telemetry unit.
- Responsibilities included twenty-four-hour unit accountability, staffing & scheduling, budgeting, personnel management, staff education, and direct patient care as needed.
- Participated & received deficiency free Joint Commission Accreditation & Department of Public Health surveys.
- Trial floor for Accountable Care Organization (ACO) patients.
- Participated in successful MNA & SEIU Union Contract Negotiations and Reduction in force procedures.
- Directly supervised 90+ employees/ 55+ FTEs and Travel Nurses.

(2009-2011) BOSTON MEDICAL CENTER (BMC) Boston, MA
Nurse Manager, General Medicine Unit

- Managed 27 bed, general medical unit including peritoneal dialysis, medicine, surgery, telemetry, chronic ventilators, and long-term seizure/EEG monitoring/surgical burr hole patients.
- Responsibilities included twenty-four-hour unit accountability, staffing & scheduling, budgeting, personnel management, staff education, patient/family rounding, and direct patient care as needed.
- Directly supervised 42+ employees/35 FTEs.
- Participated & received deficiency free Joint Commission Accreditation & Department of Public Health surveys.
- Co-Chaired Nursing Management Leadership Council to improve patient care.

(2007-Present) BROWN & ASSOCIATES, LEGAL NURSE CONSULTING, LLC Bridgewater, MA
Owner/President; Nurse Expert; Independent Certified Legal Nurse Consultant

- Serve as patient/family advocate, liaison between attorneys, healthcare providers, experts, and witnesses; provide education as needed for both plaintiff and defense cases.
- Identify & review relevant medical records, hospital policies & procedures, and other essential documents.

- Screen cases for merit; define applicable standards of care, adherences to, and deviations from standards of care.
- Assess alleged damages/ injuries and identify factors that caused or contributed to alleged damages/ injuries.
- Organize, summarize, translate, and interpret medical records.
- Identify & locate appropriate types of testifying experts; serve as nurse expert.
- Develop written reports & chronological timelines.
- Attend and assist with defense medical exams (DMEs), depositions and/or trials,

(2004-2009)
2008-2009

SOUTH SHORE HOSPITAL (SSH)

South Weymouth, MA

Trauma Injury Prevention Coordinator

- In collaboration with the Trauma Medical Director & Trauma Program Manager, developed, coordinated, implemented and evaluated hospital and community outreach prevention programs for identified SSH target populations.
- Participated in grant writing & preparation to achieve funding for programs to support injury prevention.
- Educated various members of community in injury prevention tactics: concussions, falls, seat belts, car seats, general health and wellness fairs/ clinics.
- Participated in preparation for & successfully received Level II Trauma Center Verification.

2004-2008

Nurse Manager, Orthopedic & Medical/Surgical Unit

- Managed 28 bed, inpatient orthopaedic, peritoneal dialysis, medical/surgical, and eight bed telemetry unit.
- Responsibilities included: twenty-four-hour unit accountability, staffing & scheduling, budgeting, personnel management, staff education, and direct patient care as needed.
- Directly supervised 60+ employees/38 FTEs.
- Performed daily patient rounds to ensure a culture of service excellence.
- Increased Press Ganey Scores on unit specific patient satisfaction surveys.

(1998-2003)
1999-2003

TUFTS-NEW ENGLAND MEDICAL CENTER HOSPITAL (T-NEMC) Boston, MA

Nurse Manager, General Clinical Research Center (GCRC)

- Managed ten (10) bed combined inpatient medical/surgical/telemetry unit with per diem research unit & outpatient research clinic (20-40 visits per day of phase 1-4 trials.) Patient case types included ENT, Oncology, HIV, Endocrine, Radiation, and Biologics.
- Responsibilities included: twenty-four-hour unit accountability, review, oversight, and coordination of over 100 active GCRC research (phase 1-4) protocols, staffing & scheduling, budgeting, annual report and grant preparation, personnel management,
- Maintaining records according to NIH guidelines, staff education, and direct patient care as needed.
- Participated in successful competing renewal grant submission process and National Institute for Health (NIH) site visit.

1999

Project Manager

- Coordinated and managed the following projects: Pyxis, Wireless Communication, Thermometers & Hepafilter/Isolation rooms.
- Performed needs assessment, coordinated inservices & tours with vendors, and provided educational inservices to staff members

- 1998-1999 Director of Nursing, Adult Transitional Care Unit**
- Managed twenty-one (21) bed Medicare/SNF unit according to state & federal guidelines.
 - Responsibilities included: twenty-four-hour unit accountability, staffing & scheduling, financial management (budget & PPS), personnel management, overseeing MDS/PPS process, maintaining medical records for OBRA compliance, staff education, and direct patient care as needed.
 - Chaired bi-weekly interdisciplinary care plan meetings to ensure appropriate transition of patients back to community.
 - Participated in successful Department of Public Health (DPH) site visit.
 - Due to financial constraints, closed Transitional Care Unit per hospital guidelines & DPH regulations (7/99).
 - Assisted with 100% transfer of staff members to other units per MNA guidelines.
- (1995-1998) HEBREW REHABILITATION CENTER FOR AGED (HRCA) Boston, MA**
1996-1998 Resident Care Coordinator/Assistant Nurse Manager/ Preceptor
- Managed fifty (50) bed Rehabilitation Unit on behalf of Nurse Manager.
 - Responsibilities included: unit accountability, staffing & scheduling, presenting administrative rounds & staff meetings, conducting interviews & disciplinary processes.
 - Participated in daily Physician/Nursing Rounds, coordinated all of resident care, acted as clinical resource for unit, and liaison with physicians, residents, and families.
 - Provided direct patient care as needed.
 - HRCA certified in IV insertion & blood transfusions.
 - Directed students and Nurses during clinical practicums and orientations.
- 1995-1996 Graduate Student/Researcher**
- Worked with the VP & ADON by researching & validating the need for a Nursing Fellowship/Mentorship program in Long-term care.
- (1991-1997) NEW ENGLAND MEDICAL CENTER HOSPITAL (NEMCH) Boston, MA**
1996-1997 Per Diem Registered Nurse (Please see 1994-1996)
1994-1996 General Surgical/Transplant/Intermediate Care Registered Nurse
- As Charge Nurse, assisted in management of twenty-five (25) bed acute care & three (3) bed intermediate care unit.
 - Provided care to complex medical, surgical, liver & kidney transplant, bariatric and intermediate care patients
 - Skilled in phlebotomy, chemotherapy, IV care, telemetry, tube feedings, and tracheostomy care.
 - Assessed patient needs and collaborated with disciplines to arrange appropriate follow-up care.
- 1992-1995 Preceptor**
- Directed students and Nurses during clinical practicums and orientations.
- 1993-1994 Breast Health Case Manager-Vascular Surgical Unit**
- Provided care, teaching, and follow-up care to breast health patients.
 - Inserviced all staff members in order to care for mastectomy & breast health patients.
- 1991-1994 Vascular Surgical Registered Nurse**
- As Charge Nurse, managed 21 bed acute care unit while providing care to general surgical, complex medical, and vascular patients.
 - Provided patients with knowledge for medical surgical procedures & reinforcing teaching with support groups and home care.

AWARDS & RECOGNITION:

- Add
- **Partners in Excellence Team Award** – “Acute Transfer Committee” (January 2016)
- **Massachusetts Hospital Association (MHA) Accountable Care Compass Award** (2015)
Enhancing Culture & Leadership – “Chasing Zero Harms” – Spaulding Rehabilitation Hospital, Cape Cod, Team Award

PROFESSIONAL MEMBERSHIPS:

- National Association of Orthopaedic Nurses (NAON) (2006-2017; 2019-present)
- American Association of Legal Nurse Consultants (AALNC) (2008-present)
- National Alliance of Certified Legal Nurse Consultants (NACLNC) (2007-present)
- Association of Rehabilitation Nurses (2014-present)
- International Association of Forensic Nurses (2016-2017)
- American Association of Legal Nurse Consultants- Southern New England Chapter (AALNC-SNE) Treasurer- (2013-2014, 2014-2015)
- American Association of Legal Nurse Consultants- Southern New England Chapter (AALNC-SNE) - President (2010 -2011, 2011-2012, 2012-2013, 2013-2014)
- American Association of Legal Nurse Consultants- Southern New England Chapter (AALNC-SNE) - President-Elect (2009-2010)
- Organization of Nurse Leaders (ONL) MA & RI – 4-week Leadership Academy (2011)
- American Association of Legal Nurse Consultants- Southern New England Chapter (AALNC-SNE) Member (2008-2017)
- Massachusetts Bar Association (MBA) (2008-2018)
- Massachusetts Academy of Trial Attorneys (MATA) (2008-2009)
- Emergency Nurse’s Association (2008-2009)
- South Shore Chamber of Commerce (2008-2017)
- Business Network International (BNI)- The Masters Circle (2008-2009)
- South Shore Women’s Business Network (SSWBN) (2008-2009)
- American Organization of Nurse Executives (AONE) (2006-2007)
- National Association of GCRC Nurse Managers (2000-2003)
- Organization of Nurse Leaders (formerly Massachusetts Organization of Nurse Executives (MONE) (2005-2007/ 2010-2016)

MEMBER:

MBMHU at LEMUEL SHATTUCK HOSPITAL (LSH)

- Performance & Recognition Program (PRP) Committee member (2019-present)
- Pharmacy & Therapeutics Committee (2018-present)
- Mock Joint Commission Survey Team for LSH & MA Department of Mental Health Hospitals (2018-present)
- Policy Committee (2018-present)
- Patient Council (2018-present)
- Education Committee (2018-present)
- Interview Committee (2018-present)
- Falls Committee (2018-present)
- Ethics Committee (2018-present)
- Quality Assessment Performance Improvement Committee (QAPI) (2018-present)
- First Aide Support Team (FAST) (2018-present)

- Infection Control Steering Committee

SPAULDING REHABILITATION HOSPITAL, CAPE COD

- Pharmacy & Therapeutics Committee (2014-2016)
- Falls Committee (2014-2016)
- Skin/Wound Care Committee (2014-2016)
- Patient Care Services Committee (2014-2016)
- Utilization Review Committee (2014-2016)
- Clinical Ladder Review Board (2014-2016)
- Patient Care Experience Committee (2014-2016)
- Patient Care Services Committee (2014-2016)
- Events/Parade Planning Committee (2014-2016)
- Outcomes Committee (2014-2016)
- Joint Therapy & Nursing Practice Council Committee (2014-2016)
- Professional Nurse Practice Council Committee (2014-2016)
- Rehab Aide/CNA Practice Council Committee (2014-2016)
- Accreditation Committee (2014-2016)
- Infection Control Committee (2014-2016)
- Education Committee (2015-2016)

JORDAN HOSPITAL/BETH ISRAEL DEACONESS HOSPITAL

- Operations Council (2012-2014)
- Core Values Team (2012-2014)
- Central Line Committee (2012-2014)
- Critical Pathways Committee (2012-2014)
- Falls Committee (2011-2014)
- Patient Care Services Committee (2011-2014)
- Pressure Ulcer Committee (2011-2014)
- Restraint Committee (2011-2014)
- MNA & SEIU Contract Negotiation Teams (2011-2014)
- Lean Projects- Discharge/Patient Flow Team & Trial Unit (2011-2014)

BOSTON MEDICAL CENTER

- Nursing Management Leadership Council - Co-Chair (2010-2011)
- Skin Care Team (2009- 2011)
- Falls Committee (2009-2011)
- ITS Work Rounder Task Force (2009-2011)

SOUTH SHORE HOSPITAL

- Trauma Performance Improvement (PI) Meeting (2008-2009)
- Trauma Peer Review Committee (2008-2009)
- RN Trauma Committee (2008-2009)
- Schwartz Rounds Planning Committee (2006- 2008)
- Schwartz Center Clinician Facilitator & Leadership Rep. for SSH (Fall 2006)
- Ethics Consultant Team (2006-2008)
- Clinical Ladder Review Board (2006-2008)

- Alcohol Withdrawal Task Force (2006-2008)
- Clinical Practice Council (2006-2009)
- Rapid Response Task Force/Pilot unit (2006-2008)
- Discharge Initiative Task Force/Pilot unit (2006-2008)
- Flagging Orders Task Force (2006-2008)
- Pharmacy Generated Medication Record/PMAR Task Force (2006)
- Magnet Task Force (2005-2008)
- PCS Clinical Advisory Committee (2005-2008)
- Human Resources/ Employee Relations/Problem Resolution/ Peer Review Panel (2005-2008)
- JCAHO Preparedness Task Force (2004-2008)
- Patient Observer/Sitter Task Force (2004-2005)
- Shared Governance Design & Redesign Team (2004-2008)
- Advancement & Recognition/ Clinical Ladder Design Team (2004-2008)
- Community Acquired Pneumonia (CAP) Task Force (2004-2008)
- Falls Committee (2004-2009)
- Total Joint Patient Education Classes (2004-2008)

NEW ENGLAND MEDICAL CENTER

- Nursing Informatics Council (2002-2003)
- Ill Committee (2002-2003)
- Geriatric Council (2001-2002)
- Region III Representative for GCRC Nurse Manager Group (2001-2002)
- Region III Alternate Representative for GCRC Nurse Manager Group (2000-2001)
- Patient Observation Strategy Group/Falls Assessment Task Force (2000-2003)
- National Association of GCRC Nurse Managers (2000-2003)
- Documentation Committee (2000-2003)
- Investigational Review Board (2001-2003/ voting member)
- Investigational Review Board (1999-2001/ non-voting member)
- Scientific Advisory Committee (1999-2003/ non-voting member)
- Chemotherapy Committee (1999-2003)
- Cancer Care Steering Committee (1999-2003)
- Wireless Communication Task Force (1999-2000)
- Medication System Review Team (1999-2000)
- Patient Care Delivery Team (1999-2000)

SPECIALIZED TRAINING:

LEMUEL SHATTUCK HOSPITAL (LSH)

- Mock Joint Commission Survey Team for MA Department of Mental Health Hospitals (2018-present)
- Basic Life Support (BLS) (2018-present)
- Safety Hope & Healing (2018-present)
- Diversity Training (2018-present)
- Columbia Suicide Severity Rating Scale (C-SSRS) (2018-present)
- First Aide Support Team (FAST) (2018-present)

SPAULDING REHABILITATION HOSPITAL

- Collaborative Learning Improvement Process (CLIP) (2014 & 2015)

- Nonviolent Crisis Intervention/ Crisis Prevention Intervention (CPI) (2014)
- Basic Life Support (BLS) (2014-2016; 2017)
- Advanced Cardiac Life Support (ACLS) (2015-2016)
- Team STEPPS Master Training (2015)

JORDAN HOSPITAL

- Leadership Academy (2013)
- Lean Training & Initiatives (2012-2013)
- Difficult Conversations Training (2012)
- Accountable Care Organization (ACO) training & pilot unit (2012-present)
- Basic Life Support (BLS) (2011-2013)
- Advanced Cardiac Life Support (ACLS) (2013)
- 2 Day ONS Chemotherapy & Biotherapy Course (2013)

BOSTON MEDICAL CENTER

- Basic Life Support (BLS) certified

SOUTH SHORE HOSPITAL (SSH)

- Emergency Response Training (ERT) (2004-present)
- Basic Life Support (BLS) certified
- Peritoneal Dialysis for the Hospital Nurse (Baxter & SSH training courses)

HEBREW REHABILITATION CENTER FOR AGED (HRCA)

- Basic Life Support (BLS) certified (1996-1998)
- Minimum Data Set (MDS) - received training at HRCA, NEMCH, and MECF
- Prospective Payment System (PPS)
- IV insertion & blood transfusion certified (HRCA Certification)

NEW ENGLAND MEDICAL CENTER (NEMC)

- Advanced Cardiac Life Support (ACLS) certified (1999-2001)
- Basic Life Support (BLS) certified (1991-1997, 1998-2004)
- Protecting Study Volunteers in Research (2000-2002)
- Defuse - Non-violent Crisis Intervention (2000)
- Minimum Data Set (MDS) - received training at HRCA, NEMCH, and MECF
- Prospective Payment System (PPS)

REFERENCES FURNISHED UPON REQUEST.

MIDDLESEX VICINAGE CIVIL DIVISION
P O BOX 2633
56 PATERSON STREET
NEW BRUNSWICK NJ 08903-2633

TRACK ASSIGNMENT NOTICE

COURT TELEPHONE NO. (732) 645-4300
COURT HOURS 8:30 AM - 4:30 PM

DATE: AUGUST 04, 2021
RE: WHITE PATRICIA VS COMMUNITY OPTIONS, I NC
DOCKET: MID L -004591 21

THE ABOVE CASE HAS BEEN ASSIGNED TO: TRACK 3.

DISCOVERY IS 450 DAYS AND RUNS FROM THE FIRST ANSWER OR 90 DAYS
FROM SERVICE ON THE FIRST DEFENDANT, WHICHEVER COMES FIRST.

THE PRETRIAL JUDGE ASSIGNED IS: HON THOMAS D. MCCLOSKEY

IF YOU HAVE ANY QUESTIONS, CONTACT TEAM 004
AT: (732) 645-4300 EXT 88905.

IF YOU BELIEVE THAT THE TRACK IS INAPPROPRIATE YOU MUST FILE A
CERTIFICATION OF GOOD CAUSE WITHIN 30 DAYS OF THE FILING OF YOUR PLEADING.
PLAINTIFF MUST SERVE COPIES OF THIS FORM ON ALL OTHER PARTIES IN ACCORDANCE
WITH R.4:5A-2.

ATTENTION:

ATT: THEODORE C. LEVY
FINE & STAUD
1333 RACE STREET
PHILADELPHIA PA 19107

ECOURTS

Exhibit B

FINE AND STAUD, LLC

BY: Theodore C. Levy, Esquire

Attorney I.D.: 311794

BY: Amy S. Soll, Esquire

Attorney I.D.: 63039

1333 RACE STREET

PHILADELPHIA, PA 19107-1585

215-665-0100

tlevy@fineandstaud.com

asoll@fineandstaud.com

ATTORNEYS FOR PLAINTIFF

PATRICIA WHITE, individually and as
guardian of TARAR CASSEL and
TARAR CASSEL

Plaintiffs

V.

COMMUNITY OPTIONS, INC. and
VIRTUA WILLINGBORO HOSPITAL
and LAUREL BROOK REHABILITATION &
HEALTHCARE CENTER and
POWERBACK REHABILITATION -
PISCATAWAY and JOHN DOE #1-10
(fictitious) and ABC CORPORATON #1-10
(fictitious)

Defendants

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
MIDDLESEX COUNTY

DOCKET NO. MID-L-4591-21

Civil Action

AFFIDAVIT OF SERVICE

I, THEODORE C. LEVY, ESQUIRE, being duly sworn according to law, deposes and says that he served a true and correct copy of Complaint in the above captioned matter upon Defendant, Community Options, Inc., via personal service by Guaranteed Subpoena, which was effectuated on August 6, 2021. The signed Affidavit of Service is attached here and marked as **Exhibit "A"**.

FINE AND STAUD LLC

BY:


THEODORE C. LEVY, ESQUIRE
Attorney for Plaintiff

Sworn to and subscribed
before me this 11th day
of August, 2021


Notary Public

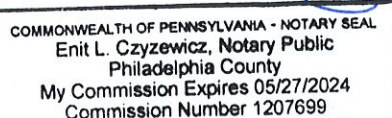


EXHIBIT A

PATRICIA WHITE, ET AL

Plaintiff

20210805171937

Superior Court Of New Jersey

VS

MIDDLESEX Venue

COMMUNITY OPTIONS INC, ET AL

Defendant

Docket Number: MID L 4591 21

Person to be served (Name and Address):

COMMUNITY OPTIONS INC.

16 FARBER RD.

PRINCETON NJ 08540

By serving: COMMUNITY OPTIONS INC.

Attorney: THEODORE C. LEVY, ESQ.

Papers Served: SUMMONS, INDIVIDUAL SHORT FORM COMPLAINT, DEMAND, CERTIFICATION, TRACK ASSIGNMENT NOTICE, AFFIDAVIT OF MERIT**AFFIDAVIT OF SERVICE**

(For Use by Private Service)

Cost of Service pursuant to R. 4:4-3(c)

\$ _____

Service Data: ☒ Served Successfully ☐ Not Served

Name of Person Served and relationship/title:

Date/Time: 8/6/2021 12:47 PMISABELLA MIKULSKA☐ Delivered a copy to him/her personallyPERSON AUTHORIZED TO ACCEPT SERVICE☐ Left a copy with a competent household member over 14 years of age residing therein (indicate name & relationship at right)☒ Left a copy with a person authorized to accept service, e.g. managing agent, registered agent, etc. (indicate name & official title at right)**Description of Person Accepting Service:**SEX: F AGE: 21-35 HEIGHT: 5'4"-5'8" WEIGHT: 100-130 LBS. SKIN: WHITE HAIR: BLONDE OTHER: _____**Unserved:**

- ☐ Defendant is unknown at the address furnished by the attorney
- ☐ All reasonable inquiries suggest defendant moved to an undetermined address
- ☐ No such street in municipality
- ☐ Defendant is evading service
- ☐ Appears vacant

☐ No response on:

Date/Time: _____

Date/Time: _____

Date/Time: _____

Other:

To Be Used Where Electronic Signature Not Available**Served Data:**

Subscribed and Sworn to me this

_____ day of _____, 20 _____

Notary Signature: _____

Name of Notary Commission Expiration**DocuSign Court Approved E-Signature**I, DAVID FILARSKI,

was at the time of service a competent adult, over the age of 18 and not having direct interest in the litigation. I declare under penalty of perjury that the foregoing is true and correct.

DAVID FILARSKI_____
Signature of Process Server08/06/2021
DateName of Private Server: DAVID FILARSKI Address: 2009 Morris Avenue UNION, NJ 07083 Phone: (800) 672-1952

Exhibit C

FINE AND STAUD, LLC

BY: Theodore C. Levy, Esquire

Attorney I.D.: 311794

BY: Amy S. Soll, Esquire

Attorney I.D.: 63039

1333 RACE STREET

PHILADELPHIA, PA 19107-1585

215-665-0100

tlevy@fineandstaud.com

asoll@fineandstaud.com

ATTORNEYS FOR PLAINTIFF

PATRICIA WHITE, individually and as
guardian of TARAR CASSEL and
TARAR CASSEL

Plaintiffs

V.

COMMUNITY OPTIONS, INC. and
VIRTUA WILLINGBORO HOSPITAL
and LAUREL BROOK REHABILITATION &
HEALTHCARE CENTER and
POWERBACK REHABILITATION -
PISCATAWAY and JOHN DOE #1-10
(fictitious) and ABC CORPORATON #1-10
(fictitious)

Defendants

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
MIDDLESEX COUNTY

DOCKET NO. MID-L-4591-21

Civil Action

AFFIDAVIT OF SERVICE

I, THEODORE C. LEVY, ESQUIRE, being duly sworn according to law, deposes and says that he served a true and correct copy of Complaint in the above captioned matter upon Defendant, Laurel Brook Rehabilitation & Healthcare Center, via personal service by Guaranteed Subpoena, which was effectuated on August 6, 2021. The signed Affidavit of Service is attached here and marked as **Exhibit "A"**.

FINE AND STAUD LLC

BY:

THEODORE C. LEVY, ESQUIRE
Attorney for Plaintiff

Sworn to and subscribed
before me this 9th day
of August, 2021

Notary Public

COMMONWEALTH OF PENNSYLVANIA - NOTARY SEAL
Enit L. Czyzewicz, Notary Public
Philadelphia County
My Commission Expires 05/27/2024
Commission Number 1207699

EXHIBIT A

PATRICIA WHITE, ET AL

Plaintiff

VS

COMMUNITY OPTIONS INC, ET AL

Defendant



20210805172310

Superior Court Of New Jersey

MIDDLESEX Venue

Docket Number: MID L 4591 21

Person to be served (Name and Address):

LAUREL BROOK REHABILITATION & HEATHCARE

3718 CHURCH RD.

MOUNT LAUREL NJ 08054

By serving: LAUREL BROOK REHABILITATION & HEATHCARE**Attorney:** THEODORE C. LEVY, ESQ.**Papers Served:** SUMMONS, INDIVIDUAL SHORT FORM COMPLAINT, DEMAND, CERTIFICATION, TRACK ASSIGNMENT NOTICE, AFFIDAVIT OF MERIT**AFFIDAVIT OF SERVICE**

(For Use by Private Service)

Cost of Service pursuant to R. 4:4-3(c)

\$ _____

Service Data: ☒ Served Successfully ☐ Not Served

Name of Person Served and relationship/title:

Date/Time: 8/6/2021 1:07 PM

DEBBIE MEANS

☐ Delivered a copy to him/her personally

MANAGING AGENT

☐ Left a copy with a competent household member over 14 years of age residing therein (indicate name & relationship at right)☒ Left a copy with a person authorized to accept service, e.g. managing agent, registered agent, etc. (indicate name & official title at right)**Description of Person Accepting Service:**

SEX: F AGE: 51-65 HEIGHT: 5'4"-5'8" WEIGHT: 161-200 LBS. SKIN: WHITE HAIR: BROWN OTHER: _____

Unserved:

- ☐ Defendant is unknown at the address furnished by the attorney
- ☐ All reasonable inquiries suggest defendant moved to an undetermined address
- ☐ No such street in municipality
- ☐ Defendant is evading service
- ☐ Appears vacant
- ☐ No response on:

Date/Time: _____

Date/Time: _____

Date/Time: _____

Other:

To Be Used Where Electronic Signature Not Available**Served Data:**

Subscribed and Sworn to me this

_____ day of _____, 20 _____

Notary Signature: _____

Name of Notary

Commission Expiration

DocuSign Court Approved E-SignatureI, THOMAS MORAGHAN,

was at the time of service a competent adult, over the age of 18 and not having direct interest in the litigation. I declare under penalty of perjury that the foregoing is true and correct.

THOMAS MORAGHAN

Signature of Process Server

08/06/2021

Date

Name of Private Server: THOMAS MORAGHAN Address: 2009 Morris Avenue UNION, NJ 07083 Phone: (800) 672-1952

Exhibit D

FINE AND STAUD, LLC

BY: Theodore C. Levy, Esquire

Attorney I.D.: 311794

BY: Amy S. Soll, Esquire

Attorney I.D.: 63039

1333 RACE STREET

PHILADELPHIA, PA 19107-1585

215-665-0100

tlevy@fineandstaud.com

asoll@fineandstaud.com

ATTORNEYS FOR PLAINTIFF

PATRICIA WHITE, individually and as
guardian of TARAR CASSEL and
TARAR CASSEL

Plaintiffs

V.

COMMUNITY OPTIONS, INC. and
VIRTUA WILLINGBORO HOSPITAL
and LAUREL BROOK REHABILITATION &
HEALTHCARE CENTER and
POWERBACK REHABILITATION -
PISCATAWAY and JOHN DOE #1-10
(fictitious) and ABC CORPORATON #1-10
(fictitious)

Defendants

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
MIDDLESEX COUNTY

DOCKET NO. MID-L-4591-21

Civil Action

AFFIDAVIT OF SERVICE

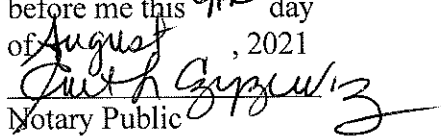
I, THEODORE C. LEVY, ESQUIRE, being duly sworn according to law, deposes and says that he served a true and correct copy of Complaint in the above captioned matter upon Defendant, Powerback Rehabilitation-Piscataway, via personal service by Guaranteed Subpoena, which was effectuated on August 6, 2021. The signed Affidavit of Service is attached here and marked as **Exhibit "A"**.

FINE AND STAUD LLC

BY:


THEODORE C. LEVY, ESQUIRE
Attorney for Plaintiff

Sworn to and subscribed
before me this 9th day
of August, 2021


Notary Public

COMMONWEALTH OF PENNSYLVANIA - NOTARY SEAL
Enit L. Czyzewicz, Notary Public
Philadelphia County
My Commission Expires 05/27/2024
Commission Number 1207699

EXHIBIT A

PATRICIA WHITE, ET AL

Plaintiff

VS

COMMUNITY OPTIONS INC, ET AL

Defendant



20210805172234

Superior Court Of New Jersey

MIDDLESEX Venue

Docket Number: MID L 4591 21

Person to be served (Name and Address):

POWERBACK REHABILITATION-PISCATAWAY

10 STERLING DRIVE

PISCATAWAY NJ 08854

By serving: POWERBACK REHABILITATION-PISCATAWAY

Attorney: THEODORE C. LEVY, ESQ.

Papers Served: SUMMONS, INDIVIDUAL SHORT FORM COMPLAINT,
DEMAND, CERTIFICATION, TRACK ASSIGNMENT NOTICE, AFFIDAVIT OF
MERIT

AFFIDAVIT OF SERVICE

(For Use by Private Service)

Cost of Service pursuant to R. 4:4-3(c)

\$ _____

Service Data: ☒ Served Successfully ☐ Not Served

Name of Person Served and relationship/title:

Date/Time: 8/6/2021 12:02 PM

WANDA MARKADA

☐ Delivered a copy to him/her personallyPERSON AUTHORIZED TO ACCEPT SERVICE☐ Left a copy with a competent household member over 14 years of age residing therein (indicate name & relationship at right)☒ Left a copy with a person authorized to accept service, e.g. managing agent, registered agent, etc. (indicate name & official title at right)**Description of Person Accepting Service:**

SEX: F AGE: 36-50 HEIGHT: 5'4"-5'8" WEIGHT: 131-160 LBS. SKIN: WHITE HAIR: BROWN OTHER: _____

Unserved:

- ☐ Defendant is unknown at the address furnished by the attorney
☐ All reasonable inquiries suggest defendant moved to an undetermined address
☐ No such street in municipality
☐ Defendant is evading service
☐ Appears vacant

☐ No response on:

Date/Time: _____

Date/Time: _____

Date/Time: _____

Other:

To Be Used Where Electronic Signature Not Available**Served Data:**

Subscribed and Sworn to me this

_____ day of _____, 20 _____

Notary Signature: _____

Name of Notary

Commission Expiration

DocuSign Court Approved E-SignatureI, MARIAN ZWIERZYNSKI,

was at the time of service a competent adult, over the age of 18 and
 not having direct interest in the litigation. I declare under penalty of
 perjury that the foregoing is true and correct.

MARIAN ZWIERZYNSKI

Signature of Process Server

08/06/2021

Date

Name of Private Server: MARIAN ZWIERZYNSKI Address: 2009 Morris Avenue UNION, NJ 07083 Phone: (800) 672-1952

Exhibit E

FINE AND STAUD, LLC

BY: Theodore C. Levy, Esquire
Attorney I.D.: 311794

BY: Amy S. Soll, Esquire
Attorney I.D.: 63039

1333 RACE STREET
PHILADELPHIA, PA 19107-1585
215-665-0100

tlevy@fineandstaud.com

asoll@fineandstaud.com

ATTORNEYS FOR PLAINTIFF

PATRICIA WHITE, individually and as
guardian of TARAR CASSEL and
TARAR CASSEL

Plaintiffs

V.

COMMUNITY OPTIONS, INC. and
VIRTUA WILLINGBORO HOSPITAL
and LAUREL BROOK REHABILITATION &
HEALTHCARE CENTER and
POWERBACK REHABILITATION -
PISCATAWAY and JOHN DOE #1-10
(fictitious) and ABC CORPORATON #1-10
(fictitious)

Defendants

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
MIDDLESEX COUNTY

DOCKET NO. MID-L-4591-21

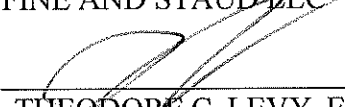
Civil Action

AFFIDAVIT OF SERVICE

I, THEODORE C. LEVY, ESQUIRE, being duly sworn according to law, deposes and says that he served a true and correct copy of Complaint in the above captioned matter upon Defendant, Virtua Willingboro Hospital, via personal service by Guaranteed Subpoena, which was effectuated on August 6, 2021. The signed Affidavit of Service is attached here and marked as **Exhibit "A"**.

FINE AND STAUD, LLC

BY:


THEODORE C. LEVY, ESQUIRE
Attorney for Plaintiff

Sworn to and subscribed
before me this 9th day
of August, 2021


Notary Public

COMMONWEALTH OF PENNSYLVANIA - NOTARY SEAL
Enit L. Czyzewicz, Notary Public
Philadelphia County
My Commission Expires 05/27/2024
Commission Number 1207699

EXHIBIT A

PATRICIA WHITE, ET AL

Plaintiff

VS

COMMUNITY OPTIONS INC, ET AL

Defendant



20210805172440

Superior Court Of New Jersey

MIDDLESEX Venue

Docket Number: MID L 4591 21

Person to be served (Name and Address):

VIRTUA WILLIANGBORO HOSPITAL
100 CHARLES EWING BLVD
EWING NJ

By serving: VIRTUA WILLIANGBORO HOSPITAL

Attorney: THEODORE C. LEVY, ESQ.

Papers Served: SUMMONS, INDIVIDUAL SHORT FORM COMPLAINT,
DEMAND, CERTIFICATION, TRACK ASSIGNMENT NOTICE, AFFIDAVIT OF
MERIT

AFFIDAVIT OF SERVICE

(For Use by Private Service)

Cost of Service pursuant to R. 4:4-3(c)

\$ _____

Service Data: ☒ Served Successfully ☐ Not Served

Name of Person Served and relationship/title:

Date/Time: 8/6/2021 2:51 PM

LISA CONSTANT

☐ Delivered a copy to him/her personally

MANAGING AGENT

☐ Left a copy with a competent household member over 14 years of age residing
therein (indicate name & relationship at right)

☒ Left a copy with a person authorized to accept service, e.g. managing agent,
registered agent, etc. (indicate name & official title at right)

Description of Person Accepting Service:

SEX: F AGE: 51-65 HEIGHT: 5'4"-5'8" WEIGHT: 161-200 LBS. SKIN: WHITE HAIR: BROWN OTHER: _____

Unserved:

- ☐ Defendant is unknown at the address furnished by the attorney
☐ All reasonable inquiries suggest defendant moved to an undetermined address
☐ No such street in municipality
☐ Defendant is evading service
☐ Appears vacant
☐ No response on:

Date/Time: _____

Date/Time: _____

Date/Time: _____

Other:

To Be Used Where Electronic Signature Not Available

Served Data:

Subscribed and Sworn to me this

_____ day of _____, 20 _____

Notary Signature: _____

_____ Name of Notary _____ Commission Expiration

DocuSign Court Approved E-Signature

I, THOMAS MORAGHAN,
was at the time of service a competent adult, over the age of 18 and
not having direct interest in the litigation. I declare under penalty of
perjury that the foregoing is true and correct.

THOMAS MORAGHAN

Signature of Process Server

08/06/2021

Date

Name of Private Server: THOMAS MORAGHAN Address: 2009 Morris Avenue UNION, NJ 07083 Phone: (800) 672-1952

Exhibit F



**ADVISORY OPINION 20-04 ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT
AND THE SECRETARY'S DECLARATION UNDER THE ACT
OCTOBER 22, 2020, AS MODIFIED ON OCTOBER 23, 2020**

The Office of the General Counsel (OGC) has received questions concerning the scope and meaning of “program planner” and “Authority Having Jurisdiction” under the Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. § 247d-6d, and its implementing secretarial Declarations. This Advisory Opinion addresses:

1. Who is a program planner under the PREP Act and the Secretary’s March 10, 2020 Declaration, as amended (Declaration)?¹
2. What is the scope of the proviso in the Declaration limiting PREP Act coverage to, *inter alia*, activities authorized by an “Authority Having Jurisdiction”?

In this Advisory Opinion, OGC re-emphasizes the breadth of PREP Act immunity. It covers a broad range of entities when such entities take reasonable steps to follow public-health guidelines and directives in using covered medical products. Such entities are not limited to healthcare professionals and healthcare companies that are part of a government response to the COVID-19 pandemic. Such entities may also include businesses, schools, and places of worship.

I. ANALYSIS

A. BACKGROUND

COVID-19 is an unprecedented global challenge. As we learn more about the highly contagious pathogen that causes COVID-19, public-health guidance and directives tend to change to reflect the new knowledge. Those changes do not always occur uniformly or simultaneously among scientists and across America’s federal, state, territorial, tribal, local, and other public-health authorities—leading to uncertainty.

Those uncertainties present potential legal risk for public and private individuals and organizations as they combat the pandemic, restore and strengthen America’s economy, ensure that transportation remains available, and provide safe environments for education and worship. Unfortunately, such perceived risks may hinder those essential efforts.

They should not. The PREP Act exists, in part, to remove legal uncertainty and risk. When an individual or organization satisfies the requirements of the PREP Act and the Declaration, that “covered person” “shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.”²

¹ See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198, 15,202 (Mar. 17, 2020) (Declaration); 85 Fed. Reg. 21,012 (Apr. 15, 2020) (First Amendment); 85 Fed. Reg. 35,100 (June 8, 2020) (Second Amendment); 85 Fed. Reg. 52,136 (Aug. 24, 2020) (Third Amendment).

² 42 U.S.C. § 247d-6d(a)(1).

Under the PREP Act, the term “covered person” includes a broad range of individuals and organizations. The term includes, among other things, anyone who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including anyone who provides a facility to administer or use a covered countermeasure in accordance with the Declaration.

The term “covered countermeasure” generally includes products (1) that the Food and Drug Administration (FDA) has approved, cleared, licensed, or authorized for emergency or investigational use; and (2) that are used to address COVID-19 or associated health threats, including harms that COVID-19 might otherwise cause.

The Declaration broadly extends PREP Act immunity to, among other things, a covered person’s conduct relating to the administration or use of covered countermeasures according to applicable public-health guidance and directives during this declared emergency.³

As we have previously explained, when a person complies with all other requirements in the PREP Act and Declaration, PREP Act immunity applies if

- the person reasonably could have believed that the person was a covered person,
- the person reasonably could have believed that the product was a covered countermeasure, and
- the person did not engage in willful misconduct that proximately caused serious physical injury or death.⁴

This Advisory Opinion discusses the broad availability of that immunity in more detail. Specifically, we focus on (1) the definition of a “program planner” and (2) the activities authorized by an “Authority Having Jurisdiction.” This Advisory Opinion also provides examples of PREP Act coverage when a “program planner” follows the public-health guidance or directives of an applicable “Authority Having Jurisdiction”—even as guidance or directives change or they conflict with other guidance or directives.

B. PROGRAM PLANNERS

Under the PREP Act, the term “covered person” includes the United States or “manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees.”⁵

³ See 85 Fed. Reg. at 15,200 (affording liability immunity to “covered persons” for “recommended activities” related to activities authorized in accordance with the public-health and medical response of the Authority Having Jurisdiction).

⁴ See Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act (May 19, 2020), <https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf> (last visited Oct. 23, 2020) (PREP Act Advisory Opinion); see also 42 U.S.C. § 247d-6d(a)(4)(B).

⁵ 85 Fed. Reg. at 151,199; 42 U.S.C. § 247d-6d(i)(2).

The PREP Act broadly defines a “program planner” using three elements: identity, function, and compliance.

Identity: A program planner is a state or local government, including an Indian tribe, a person employed by the State or local government, or other “person” who carries out the functions described immediately below. Under the PREP Act, a “person” includes “an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, state, or local government agency or department.”⁶

Function: A program planner performs certain functions, including “supervis[ing] or administer[ing] a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product.”⁷ The statute explains that those functions broadly include “establish[ing] requirements, provid[ing] policy guidance, or suppl[ying] technical or scientific advice or assistance or provid[ing] a facility to administer or use a covered countermeasure.”⁸

Compliance: Finally, to qualify as a program planner, the entity must perform those functions “in accordance with” the Declaration.⁹

The Declaration incorporates these definitions.¹⁰ The Declaration’s preamble further explains that a program planner can be a “private sector employer or community group” that “carries out the described activities.”¹¹ Nothing in the preamble or text of the Declaration limits the statutory definitions.

In short, any individual or organization can potentially be a program planner and receive PREP Act coverage. So for example, private businesses, public and private transportation providers, public and private schools, and religious organizations are all eligible for PREP Act coverage when they act in accordance with the PREP Act and the Declaration. It is important to remember, however, that the PREP Act does not provide immunity against federal enforcement actions.¹² And PREP Act immunity (but not preemption) is limited to claims for death, physical, mental or emotional injury, illness, disability or condition, fear of such harm or need for medical monitoring, and damage to property, including business interruption loss.¹³

⁶ 42 U.S.C. § 247d-6d(i)(5).

⁷ *Id.* at § 247d-6d(i)(6).

⁸ *Id.*

⁹ We use the term “entity” to include persons (*see* 1 U.S.C. § 1) and governmental units, whether state, tribal, local, or federal.

¹⁰ *See* 85 Fed. Reg. at 15,201.

¹¹ *Id.* at 15,199.

¹² *See* PREP Act Advisory Opinion at 2.

¹³ *See* 42 U.S.C. § 247d-6d; PREP Act Advisory Opinion.

C. AUTHORITY HAVING JURISDICTION

In order for there to be PREP Act coverage, there must be a PREP Act declaration.¹⁴ Among other things, such a declaration may specify whether PREP Act immunity “is effective only to a particular means of distribution as provided in subsection (a)(5) for obtaining the countermeasure, and if so, the particular means to which such subsection is effective.”¹⁵

For the COVID-19 public-health emergency, section VII of the Declaration specifies that “liability immunity is afforded to Covered Persons *only* for Recommended Activities involving Covered Countermeasures that are related to” (1) federal agreements or (2) “[a]ctivities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency.”¹⁶ An Authority Having Jurisdiction may authorize such activities through, among other things, guidance, requests for assistance, agreements, directives, or other arrangements (collectively guidance).¹⁷

Public-health guidance from an applicable Authority Having Jurisdiction that recommends or requires using covered countermeasures in certain circumstances may qualify as authorizations under the PREP Act and the Declaration. But to obtain such authorization, a covered person must follow that public-health guidance. The Declaration explains that the Authority Having Jurisdiction means the “public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.*, city, county, tribal, state, or federal boundary lines) or functional (*e.g.*, law enforcement, public health) range or sphere of authority.”¹⁸ Therefore, a covered person must comply with the public-health guidance issued by an Authority Having Jurisdiction over the person’s activity or location in order to qualify for PREP Act immunity.

If there are conflicts, PREP Act coverage will apply to a covered person using a covered countermeasure in accordance with *any* of the guidance. A conflict exists when (1) one guidance includes a recommendation or mandate that another guidance does not, and (2) there is no order of precedence under applicable law or in the guidance itself. If the applicable law or the guidance explains which authority takes precedence, a covered person must follow the guidance of the Authority Having Jurisdiction that takes precedence in order to obtain PREP Act coverage.

To illustrate, if a governor’s order on using face masks preempts or otherwise takes precedence over a mayor’s order under that state’s law, then the former must be the basis for PREP Act coverage. If one guidance says that it does not replace another guidance, the latter must be the basis for PREP Act coverage. For example, the Centers for Disease Control and Prevention’s (CDC) guidance for “Preparing for a Safe Return to School” specifies that “[t]his guidance is meant to supplement—not replace—any state, local, territorial, or tribal health and safety laws, rules, and regulations with which

¹⁴ See 42 U.S.C. § 247d-6d(a)(1).

¹⁵ 42 U.S.C. § 247d-6d(b)(2)(E).

¹⁶ See 85 Fed. Reg. at 15,202.

¹⁷ PREP Act Advisory Opinion at 2.

¹⁸ 85 Fed. Reg. at 15,202.

schools must comply.”¹⁹ So if there were a conflict between that CDC guidance and “any state, local, territorial, or tribal health and safety laws, rules, and regulations with which schools must comply,” a covered person must rely on guidance of the latter jurisdiction, and not CDC’s guidance, as the basis for PREP Act coverage.

If a guidance changes, the guidance in effect during the activity at issue will determine whether there is PREP Act coverage.

D. EXAMPLES

To illustrate more concretely the discussion above, we provide the following hypothetical examples of program planners using covered countermeasures according to the guidance of an Authority Having Jurisdiction. We use these examples to help illustrate only the PREP Act doctrines discussed above.

Testing. Federal, state, and local Authorities Having Jurisdiction issue conflicting guidance on how frequently to test at universities. Neither the state or federal law, nor the guidance from the state or federal Authorities Having Jurisdiction, preempts or supersedes the guidance from the local Authority Having Jurisdiction. A private university that has re-opened for in-person learning follows the guidance of the local Authority Having Jurisdiction in the geographic area where the university is located. The university uses a COVID-19 test that has received an Emergency Use Authorization (EUA) by the FDA. The local Authority Having Jurisdiction recommends a lower testing frequency than the state or federal Authorities Having Jurisdiction. A student who gets COVID-19 sues the university, claiming that its failure to follow the guidance from the state or federal Authority Having Jurisdiction caused the student’s injuries.

The university is a program planner because it has, among other things, “supervised or administered a program with respect to the administration ... or use of a ... qualified pandemic ... product.”²⁰ By following the guidance of the local Authority Having Jurisdiction, the university has complied with the Declaration.

The university is immune from suit and liability for loss, assuming that it has satisfied all other requirements of the PREP Act and Declaration.

Face Masks. FDA has issued an EUA authorizing “the use of face masks, including cloth face coverings, as source control for use by members of the general public, as well as [health care personnel] in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of SARS-CoV-2 during the COVID-19 pandemic.”²¹

¹⁹ *Preparing K-12 School Administrators for a Safe Return to School in Fall 2020*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/prepare-safe-return.html> (last visited Oct. 23, 2020).

²⁰ 42 U.S.C. § 247d-6d(i)(6).

²¹ *April 24, 2020 Letter to Manufacturers of Face Masks*, FDA, <https://www.fda.gov/media/137121/download> (last visited Oct. 23, 2020); *FAQs on the Emergency Use Authorization for Face Masks (Non-Surgical)*, FDA, <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-emergency-use-authorization-face-masks-non-surgical> (last visited Oct. 23, 2020).

CDC has issued guidance for “Grocery & Food Retail Workers.”²² In that guidance, “CDC recommends wearing cloth face coverings in public settings where other social distancing measures are difficult to maintain, especially in areas of significant community-based transmission.” The guidance also directs employers of grocery and food-retail workers to “[f]ollow *all* applicable local, state, and federal regulations and public health agency guidelines.”²³ A county department of health has issued a face-mask guidance recommending that those working inside a grocery store should wear cloth face covering *and* maintain social distancing.

Following CDC guidance, a grocery store in that county requires its workers to wear cloth face coverings in the public portions of its stores “where other social distancing measures are difficult to maintain.” A customer in that store gets COVID-19 and sues the grocery store, claiming that its failure to follow the county guideline contributed to the customer’s injuries.

Here, the CDC guidance directed the grocery store to follow all local, state, and federal regulations and public-health agency guidelines. The grocery store failed to follow the more stringent county guideline. Therefore, the grocery store does not have PREP Act immunity against the customer’s claim.

COVID-19 Vaccine Administration. CDC prioritizes certain populations to receive the COVID-19 vaccine while there are limited doses. A pharmacy prioritizes the CDC-designated populations for receiving the COVID-19 vaccine.

Because of that prioritization, someone seeks but does not receive the COVID-19 vaccine from the pharmacy because of the limited quantity of vaccine doses. That person gets COVID-19 and sues the pharmacy.

The pharmacy is a program planner, as set forth above. Administration of covered countermeasures, as defined in the Declaration, includes both “physical provision of the countermeasures to recipients” *or* “activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose[s] of distributing and dispensing countermeasures.”²⁴ Management and operation of countermeasure programs and decisions directly relating to public and private delivery, distribution, and dispensing of countermeasures involve decisions regarding prioritization of populations to receive countermeasures while there are limited doses. And prioritization necessarily entails temporarily withholding limited doses from some recipients, as directed by an Authority Having Jurisdiction.

By administering the COVID-19 vaccine pursuant to CDC prioritization, the pharmacy has complied with the guidance of an Authority Having Jurisdiction. The pharmacy has PREP Act coverage, assuming that it has also complied with all other requirements of the PREP Act and Declaration.

²² *What Grocery and Food Retail Workers Need to Know about COVID-19*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/grocery-food-retail-workers.html> (last visited Oct. 23, 2020).

²³ *Id.* (emphasis added).

²⁴ 85 Fed. Reg. at 15,202.

During the H1N1 pandemic, a New York court addressed a similar situation. In *Casabianca v. Mount Sinai Medical Center*, the court concluded that the PREP Act does not cover a provider that followed guidelines from CDC, the New York State Department of Health, and the New York City Department of Health. 1014 N.Y. Slip. Op. 33583(U), 2014 WL 10413521 (N.Y. Sup. Dec. 12, 2014). Under those guidelines, children, pregnant women, and hospital employees received priority for the H1N1 vaccine while there were shortages. The plaintiff's husband did not fit into any of those eligibility categories; hence, he did not receive the vaccine. The husband died after a surgical procedure and exposure to swine flu. His wife sued the provider. The court held that PREP Act immunity did not apply because it “only applies to the actual use of the vaccine.” *Id.* at *4.

The court was wrong. As the court acknowledged, “administration” is broader than the “physical provision of a countermeasure to a recipient.” *Id.* at *3. “Administration” also encompasses “activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities.” *Id.*

Activities relating to management and operation of a vaccination program pursuant to an Authority Having Jurisdiction include following CDC directions on who to vaccinate when there are limited doses. If anything, following CDC directions on vaccination priority has a closer relationship to the use of the vaccine than decisions about security and queuing recipients of the vaccine, which may result in “slip and fall injuries and vehicle accidents that are connected to the vaccination process, be it at a retail store or some other facility.” *Id.* at 4. The court recognized that PREP Act immunity can cover such injuries and accidents, but declined to interpret “activities related to management and operation of programs and locations for providing countermeasures to recipients” consistent with the plain meaning of that phrase. The plain meaning of “management and operation of programs for providing countermeasures” includes following CDC vaccine-prioritization guidelines. And if there were any doubt, the plain meaning of “activities related to” such management and operation is even broader. And that broader definition would certainly cover running a vaccination program pursuant to CDC guidelines, even assuming *arguendo* that “management and operation” does not.

II. Limitations

This Advisory Opinion may be supplemented or modified. It is intended to minimize the need for individual advisory opinions. This Advisory Opinion sets forth the current views of the Office of the General Counsel.²⁵ It is not a final agency action or a final order. Nor does it bind the Department of Health and Human Services or the federal courts. It does not have the force or effect of law.

Persons seeking PREP Act immunity are responsible for determining whether their products are “covered countermeasures,” whether a person or entity is a “covered person,” whether reasonable

²⁵ See *Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647-48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 (“The head of an executive department ... may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]”); Statement of Organization, Functions, and Delegations of Authority, 85 Fed. Reg. 54,581 54,583 (Sept. 2, 2020).

precautions have been taken to facilitate the safe use of covered countermeasures, and in general, whether immunity applies to them and their activities. In order to obtain PREP Act coverage, persons must meet all requirements set forth in the PREP Act and the Declaration.

Robert Charrow

Robert P. Charrow
General Counsel
October 23, 2020

Exhibit G

SUPREME COURT OF THE STATE OF NEW YORK NEW YORK COUNTY

PRESENT: **ALICE SCHLESINGER**
Justice

LA PART 16

Index Number : 112790/2010
CASABIANCA, ELIZABETH
vs.
MOUNT SINAI MEDICAL CENTER
SEQUENCE NUMBER : 001
DISMISS

INDEX NO. _____
MOTION DATE _____
MOTION SEQ. NO. _____

The following papers, numbered 1 to _____, were read on this motion to/for _____

Notice of Motion/Order to Show Cause — Affidavits — Exhibits _____ No(s). _____

Answering Affidavits — Exhibits _____ No(s). _____

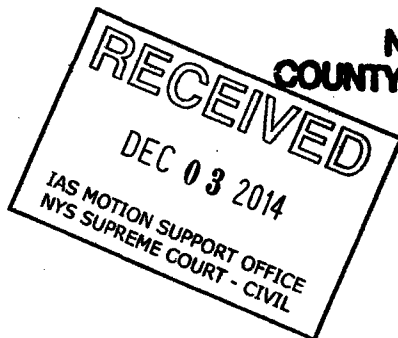
Replying Affidavits _____ No(s). _____

Upon the foregoing papers, it is ordered that this motion ~~is~~ by defendants to dismiss is denied in accordance with the accompanying memorandum decision.

FILED

DEC 03 2014

**NEW YORK
COUNTY CLERKS OFFICE**



Dated: DEC 02 2014

Alice Schlesinger
ALICE SCHLESINGER, J.S.C.

1. CHECK ONE: ☐ CASE DISPOSED ☒ NON-FINAL DISPOSITION
2. CHECK AS APPROPRIATE: MOTION IS: ☐ GRANTED ☒ DENIED ☐ GRANTED IN PART ☐ OTHER
3. CHECK IF APPROPRIATE: ☐ SETTLE ORDER ☐ SUBMIT ORDER
- ☐ DO NOT POST ☐ FIDUCIARY APPOINTMENT ☐ REFERENCE

MOTION/CASE IS RESPECTFULLY REFERRED TO JUSTICE
FOR THE FOLLOWING REASON(S):

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

-----X
ELIZABETH CASABIANCA, as Executrix of the Estate
of ANGELO CASABIANCA, Deceased, and
ELIZABETH CASABIANCA, Individually,

Plaintiff,

Index No. 112790/10
Motion Seq. No. 001

-against-

THE MOUNT SINAI MEDICAL CENTER, INC.,
KISHORE R. IYER, M.D. and GONZALO
PATRICIO RODRIGUEZ-LAIZ, M.D.,

Defendants.

FILED

DEC 03 2014

-----X
SCHLESINGER, J.:

**NEW YORK
COUNTY CLERK'S OFFICE**

The Ebola epidemic that has commanded our attention today does not stand alone in relation to various other public health emergencies that this country has experienced. Probably the most recent one, as well as the subject of this action and motion, is the Swine Flu epidemic of 2009. Its more official name is the H1N1 influenza pandemic.

For this influenza a vaccine had been developed. But in the early stages of the crisis, the vaccine was in short supply. Responding to this shortage, various hospitals, including defendant The Mount Sinai Medical Center ("Hospital"), were instructed to establish emergency preparedness committees and follow guidelines as to which individuals would receive the vaccine. These guidelines were established by the Center for Disease Control ("CDC") and the New York State and City Departments of Health ("DOH"). While this problem of supply existed, vaccines were to be dispensed to children, pregnant women and hospital employees.

In this action, which sounds in medical malpractice and wrongful death, the decedent and subject of this action, Angelo Casabianca, did not receive this vaccine. Allegedly this was because he did not fit into one of the designated categories of eligible individuals. At least that seems to be a defense offered. Clearly, one of the claims his estate is making in the complaint, which was filed in 2010, is that the Hospital and doctors departed from accepted standards of care in failing to administer the vaccine to Angelo Casabianca.

Dr. Casabianca, a podiatrist, had gone to Mount Sinai to undergo a small bowel transplant, it was performed on September 17, 2009. Due to post-surgical complications, he remained in the hospital until November 5, 2009. Then he was discharged home. Paragraph 10 of the Complaint (attached to the Opposition as Exh A) reads in its entirety:

That the defendants, the Mount Sinai Medical Center, Inc., Kishore R. Iyer, M.D. and Gonzalo Patricio Rodriguez-Laiz, M.D., its agents, servants and/or employees were careless, reckless and negligent in allowing and causing the plaintiff's decedent, ANGELO CASABIANCA, to contract the H1N1 virus, then commonly known as "swine flu"; the defendant failed to administer and/or make sure that the patient received the H1N1 immunization.

It is the plaintiff's contention that the decedent, being in a weakened condition from an intestinal transplant following the bowel resection, developed pneumonia, was exposed to the swine flu, and died on November 13, 2009.

The instant motion, based on a defense preserved in the defendants' Answer, asserts that this Court lacks subject matter jurisdiction and thus the action must be

dismissed. The argument is premised on an Act passed by Congress in 2005 known as The Public Readiness and Emergency Preparedness Act (“PREP”) and codified at 42 USC §247d-6d. That law provides immunity from tort liability for manufacturers, distributors and administrators of the vaccine during a public health emergency and further provides that the sole remedy resulting from injury would be under the Countermeasures Injury Compensation Program (“CICP”).¹ Also, PREP preempts State law, which means that any action associated with injury from a vaccine must be brought in Federal Court. See, 42 USC §247d-6d(b)(8) .

The defendants here assert that the Hospital and the named doctors are covered under the PREP Act, meaning that this action, a tort action brought against them in State court, must be dismissed. However, the opposition argues that PREP is irrelevant to this action because, to be applicable, the vaccine must have been administered. It is undisputed here that the vaccine was never administered. That, according to the plaintiff as previously stated, was the problem.

Therefore, the issue before this Court is how to interpret PREP. Should it be given the broad interpretation urged by the defense so as to adopt the “statute’s sweeping immunity” (Reply, p 4, ¶2), or rather should it be given the limited construct urged by the plaintiff?

Interestingly, few cases have been published dealing with PREP, and none actually addresses this issue. One decision cited by moving counsel, arguably in support of her position, is *Parker v Saint Lawrence County Public Health Dept*, 102

¹The act uses the word “countermeasure” as a substitute for vaccine.

AD3d 140 (3rd Dep't 2012). However, that opinion revolved around the issue of whether the PREP Act preempted plaintiff's state law claims for negligence and battery. The *Parker* action concerned plaintiff's daughter, a kindergarten student who, in December of 2009, had been inoculated with the H1N1 vaccine at a County clinic without parental consent.

The appellate court in *Parker* reversed the trial court and dismissed the complaint, broadly construing the preemption clause found within the Act. In arriving at this decision, the Third Department (at 144) found support in alternative relief included in the Act:

Notably, Congress created an alternative administrative remedy — the Countermeasures Injury Compensation Program — for covered injuries stemming from countermeasures taken in response to the declaration of a public health emergency (see 42 USC §247d-6e(a); 74 Fed Reg at 51154), as well as a separate federal cause of action for wrongful death or serious physical injury caused by the willful misconduct of covered individuals or entities (see 42 USC §247d-6d[d]).

However, contrary to defense counsel's argument, this opinion does not aid in the decision making here because the little girl in *Parker* did receive the vaccine, while Dr. Casabianca in this case did not.

In Reply, moving counsel directs this Court to the words of the statute itself. That approach is the right one here, particularly since there is an absence of case law to aid in statutory interpretation. However, this Court disagrees with counsel's conclusions as to the application of the statute.

As earlier noted in this decision, “countermeasure” as used in the Act means vaccine. It is unclear why this substitution was made and the word countermeasure used in place of the word vaccine. Perhaps the word has a broader context, including other medical solutions in addition to vaccines. But what is clear is that whenever the topic of immunity from suit is discussed, qualifying words are always used. What are those words? They are “resulting from the administration to or the use by an individual of a covered countermeasure...”

An example is included in 42 USC §247-6d(a) entitled “Liability protections” and subdivision (1) entitled “In general.” The entire clause (with emphasis added) reads as follows:

Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or **resulting from the administration to or the use by an individual of a covered countermeasure** if a declaration under subsection (b) of this section has been issued with respect to such countermeasure.

The referenced subsection (b) is entitled “Declaration by Secretary.” It relates to the circumstances wherein the Secretary of Health and Human Services determines that a disease constitutes a public health emergency, thus triggering the implementation of the statutory protections of the Act.

Section 247d-6d(a)(3) says (with emphasis added) that:

Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if --

(A) the countermeasure was **administered or used** during the effective period of the declaration that was issued under subsection (b) of this section with respect to the countermeasure;

(B) the countermeasure was **administered or used** for the category of diseases, health conditions, or threats to health specified in the declaration; and

(C) in addition, in the case of a covered person who is a program planner or qualified person with respect to the **administration or use** of the countermeasure, the countermeasure was **administered to or used** by an individual who [was in a population or geographic area specified in the declaration].

The Act excludes from its protections instances where willful misconduct was proved by the plaintiff (not this case). Subsection (c) sets forth the definition of willful misconduct, and paragraph (4) of that subsection, entitled “Defense for acts or omissions taken pursuant to Secretary’s declaration,” states that an individual “shall not have engaged in ‘willful misconduct’ as a matter of law where [the individual] acted consistent with applicable directions, guidelines or recommendations by the Secretary regarding the **administration or use** of a covered countermeasure...” (emphasis added).

In that same subsection, the Act states that one of the documents needed to prove that a patient suffered injury as a result of the vaccine is an affidavit from a non-treating physician. The physician must give reasons for his/her belief that the patient suffered serious physical injury or death “and that such injury or death was proximately caused by the **administration or use** of a covered countermeasure” (emphasis added).

In defendants' Reply, a 2012 Amendment to PREP is provided to the Court as Exhibit 1. Counsel quotes from two paragraphs, both under Section IX entitled "Administration of Covered Countermeasures." The first paragraph is quoted in its entirety, but in the second, certain parts are omitted. Both paragraphs are quoted below in their entirety with emphasis added, including part of a sentence not particularly relevant to the issues here.

As clarified, the definition of "administration" extends only to ***physical provision of a countermeasure to a recipient***, such as vaccination or handing drugs to patients, ***and to activities related to management and operation of programs and locations for providing countermeasures to recipients***, such as decisions and actions involving security and queuing, ***but only insofar as those activities directly relate to the countermeasure activities***. Claims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from ***the administration to or use by*** an individual of a Covered Countermeasure consistent with the terms of a declaration issued under the Act. Under the Secretary's definition, these ***liability claims are precluded if the claims allege an injury caused by physical provision of a countermeasure to a recipient, or if the claims are directly due to conditions of delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites***.

Thus, it is the Secretary's interpretation that, ***when a declaration is in effect, the Act precludes***, for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or ***negligence by a healthcare provider in prescribing the wrong dose***,

absent willful conduct. Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control.² However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's ***administration or use***. In each case, whether immunity is applicable will depend on the particular facts and circumstances.

In this Court's opinion, the above-quoted provisions do not support the defendants' position that the Act applies here. This section continues to emphasize that the "administration" of the vaccine applies to the "physical provision of a countermeasure to a recipient". The language makes clear that the vaccine must be administered to or used by a patient. The amendment broadens the scope of persons covered by the Act, but it still only applies to the actual use of the vaccine in the manner in which it was intended; i.e., for "the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a declaration issued under the Act".

Again, the injury must be one "caused by physical provision of a countermeasure to a recipient". In other words, something bad, perhaps not anticipated, has occurred from the administration or use of the vaccine, no matter what circumstances led to that

² The portion that follows was omitted from the Reply papers.

use. Nothing is spoken of regarding a decision not to use the vaccine or of a failure to use it, whenever that decision was made or that failure may have occurred.

In the second paragraph quoted above, the language used clarifies that immunity is extended to slip and fall injuries and vehicle accidents that are connected to the vaccination process, be it at a retail store or some other facility. But a slip and fall or automobile accident not directly connected to the administration or use of the vaccine will not be exempt from liability.

The Act consistently speaks of administering or using the countermeasure. It appears to say, in the manner of common usage of words, that absent willful misconduct, when something bad happens to a person who has received a covered countermeasure (i.e., a vaccine), whichever individual is responsible for that bad result is immune from liability.

Further support for this interpretation is found in Section XIV of the above-reference 2012 Amendment, entitled “Countermeasures Injury Compensation Program”. The first line of that clause reads in relevant part as follows:

... the PREP Act authorizes a Countermeasures Injury Compensation Program (CICP) to provide benefits to eligible individuals [or their beneficiaries] who sustain a serious physical covered injury or die as a direct result of the **administration or use** of a Covered Countermeasure.

Would any sensible person (including lawyers) seriously argue that someone like the plaintiff here, whose decedent never received the vaccine, could apply for such compensation? Certainly, Mrs. Casabianca could not avail herself of this relief. In the case of her husband, for whatever reasons, the vaccine (the covered countermeasure)

was not given. It was never administered to him or used by someone providing it to him. Thus, a claim for compensation pursuant to PREP could not be made.

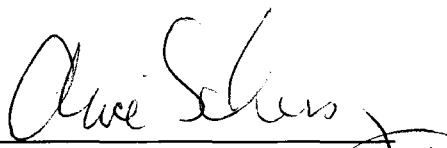
However, a claim that could be made and in fact has been made here is that Dr. Casabianca's treating physicians, by deciding not to provide him with the vaccine, committed malpractice, which was a cause of his death. Such a cause of action is in no way covered by PREP, and the immunity from suit claimed by the defendants here simply does not exist.

Accordingly, it is hereby

ORDERED that defendants' motion to dismiss is in all respects denied.

Dated: December 2, 2014

DEC 02 2014


ALICE SCHLESINGER

FILED
DEC 03 2014
NEW YORK
COUNTY CLERK'S OFFICE

Exhibit H



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
Washington, D.C. 20201**ADVISORY OPINION ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT AND
THE MARCH 10, 2020 DECLARATION UNDER THE ACT
APRIL 17, 2020, AS MODIFIED ON MAY 19, 2020****Purpose of this Advisory Opinion**

On March 10, 2020, the Secretary of Health and Human Services (Secretary) issued a Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), effective February 4, 2020, for certain medical products to be used against COVID-19. *See* 85 Fed. Reg. 15,198, 15,202 (March 17, 2020); *see also* Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e.

We have received requests for advisory opinions, especially from those donating goods and services, on whether various activities qualify for PREP Act immunity. The Office of the General Counsel will make every effort to respond to each request. But we have limited resources, especially in this time of national emergency. To minimize the need to request an advisory opinion, we issue this omnibus advisory opinion that should address most questions and concerns about the scope of PREP Act immunity during the Coronavirus disease 2019 (COVID-19) pandemic.

This advisory opinion sets forth the current views of the Office of the General Counsel.¹ It is not a final agency action or a final order. Nor does it bind HHS or the federal courts. It does not have the force or effect of law.

The PREP Act

PREP Act immunity applies to any “covered person” with respect to all “claims for loss” caused by, arising out of, relating to, or resulting from the “administration” or the “use” of a “covered countermeasure” if a declaration has been issued with respect to that countermeasure. 42 U.S.C. § 247d-6d(a)(1). We often receive questions about whether a medical product is a covered countermeasure, whether a person is a covered person, and whether a specific activity qualifies as use or administration of a covered countermeasure.

Therefore, this advisory opinion

- provides a list of covered countermeasures subject to an Emergency Use Authorization (EUA);²

¹ *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647-48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 (“The head of an executive department ... may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]”).

² *See* Appendix A, <https://www.fda.gov/media/136702/download> Appendix B, <https://www.fda.gov/media/136832/download>.

- advises that an entity or individual who complies with all other requirements of the PREP Act and the conditions of the Secretary's declaration will not lose PREP Act immunity—even if the medical product at issue is *not* a covered countermeasure—if that entity or individual reasonably could have believed that the product was a covered countermeasure;
- advises that a person who complies with all other requirements of the PREP Act and the conditions of the Secretary's declaration will not lose PREP Act immunity—even if the person at issue is *not* a covered person—if the entity or individual reasonably could have believed that the person was a covered person; and
- sets forth HHS's view that covered persons should take, and document, reasonable precautions under the current emergent circumstances to facilitate the safe use or administration of covered countermeasures and to make those documents publicly and easily available.

If all requirements of the PREP Act and the declaration are met, immunity covers claims for loss sounding in tort or contract, as well as claims for loss relating to compliance with local,³ state, or federal laws, regulations, or other legal requirements. Immunity applies when a covered person engages in activities related to an agreement or arrangement with the federal government, or when a covered person acts according to an Authority Having Jurisdiction to respond to a declared emergency. We interpret these two conditions broadly to include (1) any arrangement with the federal government, or (2) any activity that is part of an authorized emergency response at the federal, regional, state, or local level. Such activities can be authorized through, among other things, guidance, requests for assistance, agreements, or other arrangements. Because the Secretary issued a Public Health Emergency declaration on January 31, 2020, effective as of January 27, 2020, the immunity granted by the PREP Act under this declaration applies regardless of whether state or local authorities have declared states of emergencies.

A few caveats about PREP Act immunity: *First*, PREP Act immunity is not absolute. For example, the PREP Act does not provide immunity against federal enforcement actions brought by the federal government—whether civil, criminal, or administrative. Nor does the PREP Act provide immunity against suit and liability for claims under federal law for equitable relief. PREP Act immunity (exempting preemption) is also limited to claims for personal injury or damage to property. *Second*, the PREP Act replaces certain damages claims that would normally be brought in court with a no-fault compensation system outlined at 42 C.F.R. pt. 110. *Third*, PREP Act immunity must be read in light of the PREP Act's broad, express-preemption provision.⁴

³ While PREP Act immunity does not expressly extend to local laws, the Act expressly preempts any State and local law that “is different from, or is in conflict with, any requirement applicable under [the PREP Act].” 42 U.S.C. § 247d-6d(b)(8).

⁴ Under § 247d-6d(b)(8)(A), (1) “no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that is different from, *or is in conflict with*, any requirement applicable under this section”

Covered Countermeasures

The PREP Act authorizes the Secretary to issue a declaration to provide liability immunity to certain individuals and entities (covered persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (covered countermeasures). Under the March 10, 2020 declaration, covered countermeasures are any

antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.

85 Fed. Reg. 15,198, 15,202 (March 17, 2020).

Any drug, device, or biological product that is approved, cleared, or licensed by the FDA and is used to diagnose, mitigate, prevent, treat, cure, or limit the harm of COVID-19 is a covered countermeasure. The Coronavirus Aid, Relief, and Economic Security (CARES) Act § 3103, Pub. L. No. 116-136 (March 27, 2020), amended the PREP Act to add respiratory protective devices to the list of covered countermeasures so long as they are NIOSH approved and determined by the Secretary to be a priority for use during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act.⁵ *See* 42 U.S.C. § 247d, 247d-6d(i)(1)(D). Any drug, device, or biological product authorized for emergency use with respect to COVID-19 under an EUA, described in Emergency Use Instructions (EUI) issued by the CDC, or being researched under certain investigational provisions (*i.e.*, IND, IDE) to treat COVID-19 is a covered countermeasure. *See* 21 C.F.R. pts. 312 and 812. In addition, as noted above, the CARES Act amended the PREP Act to include certain respiratory protective devices. These requirements apply equally to products held in the public and private sectors.

Covered countermeasures include, among other things, a “qualified pandemic or epidemic product.” *See* 42 U.S.C. § 247d-6d(i)(1)(A). The term “qualified pandemic or epidemic product” means

a drug ... biological product ... or device [as] defined ... [in] the Federal Food, Drug, and Cosmetic Act ... that is

(A) (i) a product manufactured, used, designed, developed, modified, licensed, or procured— (I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or (II) to limit the harm such pandemic or epidemic might otherwise cause;

and (2) relates to, among other things, use or administration of the covered countermeasure. (Emphasis added).

⁵ The Secretary issued an amendment to the Declaration effective March 27, 2020 to address this statutory change. 85 Fed. Reg. 21,012 (April 15, 2020).

- (ii) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); or
- (iii) a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii); and

- (B) (i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 351 *et seq.*] or licensed under section 262 of this title;
- (ii) the object of research for possible use as described by subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 355(i), 360j(g)]; or
- (iii) authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 360bbb–3, 360bbb–3a, 360bbb–3b].

42 U.S.C. § 247d-6d(i)(7).

Thus, in order to meet the definition of a qualified pandemic or epidemic product, a product

- (1) must be used for COVID-19; and
- (2) must be
 - (a) approved, licensed, or cleared by FDA;
 - (b) authorized under an EUA;
 - (c) described in an EUI; or
 - (d) used under either an Investigational New Drug (IND) application or an Investigational Device Exemption (IDE).⁶

The number of products used for COVID-19 that are approved, licensed, or cleared are too numerous to list. But we have found that industry has often sought clarity regarding whether certain products, including diagnostic tests and personal protective equipment (PPE), are covered by EUAs. Footnote 2, above, links to a list those products that are covered by EUAs. We hope that this list proves helpful. HHS will use its best efforts to regularly update that list, although there may be a lag between the actual issuance of the EUA by FDA and the product’s appearance on the list.

Given the broad scope of PREP Act immunity, Congress did not intend to impose a strict-liability standard on covered persons for determining whether a product is a covered countermeasure. Instead, we believe that a person or entity that otherwise meets the requirements for PREP Act immunity will not lose that immunity—even if the product is *not* a covered countermeasure—if that person or entity reasonably could have believed that the product was a covered countermeasure. *See, e.g.*, 42 U.S.C. § 247d-6d(a)(4)(B) (applying the “reasonably-could-have-believed” standard to predicate

⁶ While certain information about products under an IND or IDE is confidential commercial information and not subject to disclosure, some information is available to the public on clinicaltrials.gov.

requirements for PREP Act immunity not involving the actual use and administration of covered countermeasures).

For example, FDA has issued EUAs for certain COVID-19 tests and PPE. A covered person purchases 500,000 tests or respirators that appear to be authorized under an EUA. The covered person has taken reasonable steps—under the current, emergent circumstances—to substantiate the authenticity of the products. But it turns out that some or all of the products are counterfeit. Under those circumstances, we believe that the person would be immune against a claim arising out of the use of a counterfeit test or respirator.

Covered Person

The PREP Act provides immunity to a “covered person” for certain activities (*e.g.*, manufacturing, distributing, using, or administering) involving a “covered countermeasure,” as defined in the PREP Act and delineated in a PREP Act declaration issued by the Secretary. The term “covered person,”

when used with respect to the administration or use of a covered countermeasure, means—

(A) the United States; or

(B) a person or entity that is—

- (i) a manufacturer of such countermeasure;
- (ii) a distributor of such countermeasure;
- (iii) a program planner of such countermeasure;
- (iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or
- (v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

42 U.S.C. § 247d-6d(i)(2). We have received questions about the meaning of “program planner” and “qualified person.”

The term “program planner” means

a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with [the Secretary’s declaration].

42 U.S.C. § 247d-6d(i)(6).

Under the Secretary’s declaration, “[A] private sector employer or community group or other ‘person’ can be a program planner when it carries out the described activities.” 85 Fed. Reg. at 15,202.

The term “qualified person,” when used

with respect to the administration or use of a covered countermeasure, means— (A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) a person within a category of persons so identified in a declaration by the Secretary.

42 U.S.C. § 247d-6d(i)(8).

With respect to that second category, the Secretary, through Section V of his declaration, has determined that qualified persons also include

[a]ny person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an emergency[.]

85 Fed. Reg. at 15,202.

Therefore, an Authority Having Jurisdiction has broad powers to extend PREP Act immunity to additional individuals as part of a public health and medical emergency response. The Authority Having Jurisdiction does so by authorizing “any person” to “prescribe, administer, deliver, distribute or dispense the Covered Countermeasures.” Section VII of the declaration explains that “[t]he Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, tribal, state, or federal boundary lines) or functional (e.g., law enforcement, public health) range or sphere of authority.” *Id.* As the lead federal public-health agency that has legal responsibility and authority for responding to the COVID-19 emergency, HHS is an Authority Having Jurisdiction, but it is not the only Authority Having Jurisdiction to respond to the COVID-19 emergency.

The following is an example of a qualified person under Sections V and VII of the declaration. In response to the COVID-19 emergency, the HHS Office of the Assistant Secretary for Health (OASH) issued guidance for licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the FDA has authorized. Such tests are covered countermeasures under the declaration. Thus, under Sections V and VII of the declaration, such pharmacists are covered persons. Specifically, they are qualified persons, as they are acting in accordance with guidance from HHS—an Authority Having Jurisdiction to respond—following a declared emergency by the Secretary. The pharmacists are covered as qualified persons (and hence as covered persons) even if they may not be

licensed or authorized by the State to prescribe the tests pursuant to § 247d-6d(i)(8)(A)), because they fit within the alternative definition of “qualified persons” pursuant to paragraph § 247d-6d(i)(8)(B), as provided by the Secretary in the declaration.

As with covered countermeasures, an entity or person that otherwise meets the requirements for PREP Act immunity will not lose that immunity—even if the entity or person is *not* a covered person—if that entity or person reasonably could have believed, under the current, emergent circumstances, that the person was a covered person. *See, e.g.*, 42 U.S.C. § 247d-6d(a)(4)(B).

For example, a pharmacy allows its licensed pharmacists to order FDA-authorized, self-swab COVID-19 tests pursuant to the OASH guidance. Notwithstanding the pharmacy’s reasonable-compliance measures to ensure current licensure, it turns out that one of the pharmacists had inadvertently allowed his license to expire. Under those circumstances, the pharmacy would still be immune against a lawsuit relating to the COVID-19 test prescribed by that pharmacist.

Reasonable Precautions

Under the PREP Act, immunity is broad. As a general matter, a covered person is immune from liability for all claims for loss except for willful misconduct that proximately caused death or serious injury. 42 U.S.C. § 247d-6d(c)(3). Suits alleging an exception to immunity for covered persons can only be brought before a three-judge court in the United States District Court for the District of Columbia. 42 U.S.C. § 247d-6d(e)(1), (5). And to prevail, a plaintiff must establish, by clear and convincing evidence, that the willful misconduct proximately caused death or serious injury. 42 U.S.C. § 247d-6d(c)(3).

But even then, certain acts or omissions remain immune from suit. For example, under 42 U.S.C. § 247d-6d(c)(4),

Notwithstanding any other provision of law, a program planner or qualified person shall not have engaged in “willful misconduct” as a matter of law where such program planner or qualified person acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure that is specified in the declaration under subsection (b), provided either the Secretary, or a State or local health authority, was provided with notice of information regarding serious physical injury or death from the administration or use of a covered countermeasure that is material to the plaintiff’s alleged loss within 7 days of the actual discovery of such information by such program planner or qualified person.

And under 42 U.S.C. § 247d-6d(c)(5), certain acts or omissions by a manufacturer or distributor and “subject to regulation by this chapter or by the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 *et seq.*]” will not constitute willful misconduct if (1) “neither the Secretary nor the Attorney General has initiated an enforcement action with respect to such act or omission” or (2) “such an enforcement action has been initiated and the action has been terminated or finally resolved without a covered remedy.”

Nevertheless, HHS encourages all covered persons using or administering covered countermeasures to document the reasonable precautions they have taken to safely use the covered countermeasures.

For example, consider a distributor of medical products that sources PPE from a new supplier abroad in a good-faith attempt to quickly deliver PPE to American communities affected by COVID-19. Among other things, that distributor assesses the supplier's facility to confirm that the supplier actually manufactures the PPE. The distributor also confirms that the supplier has quality-control processes in place.

Under those circumstances, the distributor may wish to make available to the purchaser information about the reasonable efforts that the distributor had taken to safely use the covered countermeasures. Purchasers such as hospitals would then be able to make more informed decisions about how best to use the PPE. Overall, this would provide greater transparency in implementing the PREP Act.

Compensation for Injuries

The PREP Act, like workers' compensation or the National Vaccine Injury Compensation Program, substitutes a no-fault, speedy compensation system in place of expensive and uncertain litigation. Those who have been seriously injured or died as the direct result of a covered countermeasure administered or used under a declaration may seek compensation from the Covered Countermeasures Process Fund. Requests for benefits must be made to the Health Resources and Services Administration's Countermeasures Injury Compensation Program (CICP). Compensation for serious injuries may be available to eligible requesters under CICP.

A serious injury generally means a physical injury that warranted hospitalization (whether or not the person was actually hospitalized) or that led to a significant loss of function or disability. 42 C.F.R. § 110.3(z). CICP pays reasonable and necessary medical benefits. CICP also pays lost wages to eligible recipients. Death benefits may also be available to certain survivors of eligible individuals who died as a direct result of the administration or use of a covered countermeasure. CICP is payer of last resort. So benefits are reduced by the amounts payable by other public and private third-party payers (such as health insurance and workers' compensation). The regulations implementing the CICP are at 42 C.F.R. pt. 110.

Compensation for injuries is more limited than the liability immunity afforded under the PREP Act. As described above, the PREP Act provides immunity for all claims for loss. But CICP will provide compensation only for eligible claims of serious physical injury or death. CICP will not compensate claims related to emotional injury, fear of injury, business losses, or other types of claims for which immunity is provided. Information about this program can be found at <https://www.hrsa.gov/cicp/about/index.html> or by calling 855-266-2427.

Limitations

This Advisory Opinion may be supplemented or modified. It is intended to minimize the need for individual advisory opinions.

Persons seeking PREP Act immunity are responsible for determining whether their products are covered countermeasures, whether a person or entity is a covered person, whether reasonable precautions have been taken to facilitate the safe use of covered countermeasures, and in general, whether immunity applies to them and their activities.

Robert P. Charrow

Robert P. Charrow
General Counsel
May 19, 2020

Exhibit I



**ADVISORY OPINION 21-01 ON THE
PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT
SCOPE OF PREEMPTION PROVISION
JANUARY 8, 2021**

Following the issuance by the Secretary on December 3, 2020, of the Fourth Amendment to his Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, we have received questions as to whether the PREP Act applies where a covered person declined to use a covered countermeasure when it arguably ought to have been used.¹ *See* 85 Fed. Reg. 79,190 (Dec. 9, 2020). These inquiries were stimulated, as we understand, by a spate of recent lawsuits, most involving nursing homes and other healthcare facilities, where patients or their estates allege that patients contracted COVID-19 because the facility, among other things, failed to provide its staff with personal protective equipment (“PPE”), failed to teach the staff how to properly use that equipment, or failed to ensure that its staff used the PPE that it had been given. This Advisory Opinion addresses these questions in the context of our administration of the PREP Act and the Secretary’s PREP Act Declaration, as amended.

I. Analysis

There has been a growing number of suits related to the use or non-use of covered countermeasures against COVID-19, including PPE. These cases tend to be filed in state courts alleging a variety of state law-based torts. In this “jurisprudential Kabuki dance” (*Maine Public Utilities Com’n v. F.E.R.C.*, 625 F.3d 754, 758 (D.C. Cir. 2010)), defendants file removal petitions and plaintiffs respond with remand motions. To resolve the remand motions, courts first assess whether the doctrine of complete preemption applies. Ordinary preemption is a defense and does not support Article III subject matter jurisdiction (usually under 28 U.S.C. § 1331), a prerequisite for removal. *See Merrell Dow Pharmaceuticals v. Thompson*, 478 U.S. 804 (1986). In contrast, complete preemption is “really a jurisdictional rather than a preemption doctrine, [as it] confers exclusive federal jurisdiction in certain instances where Congress intended the scope of a federal law to be so broad as to entirely replace any state-law claim.” *Marin General Hosp. v. Modesto & Empire Traction Co.*, 581 F.3d 941, 945 (9th Cir. 2009) (quoting *Franciscan Skemp Healthcare, Inc. v. Cent. States Joint Bd. Health & Welfare Trust Fund*, 538 F.3d 594, 596 (7th Cir. 2008) (internal quotations omitted)). Relatively few statutes completely preempt.

¹ The PREP Act is the Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-148, div. C, § 2, 119 Stat. 2818 (Dec. 30, 2005), codified at 42 U.S.C. §§ 247d-6d, 247d-6e. It has been amended through the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, Pub. L. No. 113-5, title IV, § 402(g)(2), (3), 127 Stat. 196 (Mar. 13, 2013) and further amended by § 6005 of the Families First Coronavirus Response Act, Pub. L. No. 116-127, 134 Stat. 177 (March 18, 2020) and § 3103 of the Coronavirus Aid Relief, and Economic Security Act, Pub. L. No. 116-136, 134 Stat. 281 (March 27, 2020).

A. The PREP Act is a “Complete Preemption” Statute

The Supreme Court first articulated the doctrine of complete preemption as a basis for federal question removal jurisdiction under 28 U.S.C. § 1441(a) in *Avco Corp. v. Aero Lodge No. 735, Intern. Ass'n of Machinists and Aerospace Workers*, 390 U.S. 557, 559 (1968) (holding that the Labor Management Relations Act, 1947 completely preempted state court jurisdiction). Thereafter, the doctrine was extended to the Employee Retirement Income Security Act of 1974 in 1987, the National Bank Act in 2003, and the Air Transportation Safety and System Stability Act in 2005. *See Metropolitan Life Insurance Co. v. Taylor*, 481 U.S. 58 (1987) (ERISA completely preempts state law); *Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004) (the same); *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 7–11 (2003) (National Bank Act completely preempts); *In re WTC Disaster Site*, 414 F.3d 352, 375 (2d Cir. 2005) (Air Transportation Safety and System Stability Act completely preempted state claims and ousted state courts of jurisdiction by creating an exclusive federal cause of action). The *sine qua non* of a statute that completely preempts is that it establishes either a federal cause of action, administrative or judicial, as the only viable claim or vests exclusive jurisdiction in a federal court. The PREP Act does both.

Once complete preemption attaches, the district court is usually obligated to dismiss the case as pleaded, either because no federal cause of action is alleged or the exclusive initial venue is a federal administrative agency.

All that is well and good, but it does not address the issue that appears to have perplexed district courts, namely when is the PREP Act triggered. District courts appear to have labored hard attempting to ordain whether the non-use of a covered countermeasure triggers the PREP Act and its complete preemption regime. At one extreme, plaintiff may have pleaded that the facility failed *in toto* to provide any of its staff or patients with any PPE, a covered countermeasure if NIOSH approved or FDA cleared or waived. Other plaintiffs allege that the quantity of PPE was inadequate, that staff were not timely provided PPE or that staff were not adequately trained to use PPE. The latter three complaints reflect many of the complaints that we have reviewed.

The PREP Act's immunity provision, which triggers exclusive federal jurisdiction, states as follows:

Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

Public Health Service Act § 319F-3(a)(1), 42 U.S.C. § 247d-6d(a)(1) (emphasis supplied).

The PREP Act goes on to provide that its immunity

applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal

relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

Id. at § 319F-3(a)(2)(B), 42 U.S.C. § 247d-6d(a)(2)(B) (emphasis supplied).

Some district courts have interpreted the scope of the immunity in subparagraph (B) as requiring “use.” Under this view, if a covered countermeasure were not used, then there is no PREP Act immunity. According to one court, “[t]here is simply no room to read [the PREP Act] as equally applicable to the non-administration or non-use of a covered countermeasure.” *Lutz v. Big Blue Healthcare, Inc.*, ___F. Supp. 3d ___, 2020 WL 4815100, at *8 (D. Kan. 2020) (emphasis in original) (granted remand motion).

However, this “black and white” view clashes with the plain language of the PREP Act, which extends immunity to anything “relating to” the administration of a covered countermeasure. For example, consider a situation where there is only one dose of a COVID–19 vaccine,² and a person in a vulnerable population and a person in a less vulnerable population both request it from a healthcare professional. In that situation, the healthcare professional administers the one dose to the person who is more vulnerable to COVID–19. In that circumstance, the failure to administer the COVID–19 vaccine to the person in a less-vulnerable population “relat[es] to . . . the administration to” the person in a vulnerable population. The person in the vulnerable population was able to receive the vaccine only because it was not administered to the person in the less-vulnerable population. Prioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority’s directive, can fall within the PREP Act and this Declaration’s liability protections. There can potentially be other situations where a conscious decision not to use a covered countermeasure could relate to the administration of the countermeasure. In contrast, the failure to purchase any PPE, if not the outcome of some form of decision-making process may not be sufficient to trigger the PREP Act.

Where a facility has been allocated a scarce therapeutic purchased by the federal government and that facility fails to administer that therapeutic to an individual who meets the requirements of the FDA’s authorization, approval, or license, and whose physician prescribes that therapeutic, then the facility’s refusal to administer that therapeutic could still trigger the PREP Act assuming the non-use of the therapeutic was the result of conscious decision-making. However, the facility may still be liable under the PREP Act, if the plaintiff alleges that the decision to deny him or her the therapeutic was wanton and willful and resulted in death or serious injury. *See* 42 U.S.C. § 247d-6d(d)-(e). Such a case would be transferred to the District Court for the District of Columbia for resolution by a three-judge panel. The facility may also be subject to a federal enforcement action.

² For simplicity, this example assumes a patient only requires one dose of the vaccine.

The language of the PREP Act itself supports a distinction between allocation which results in non-use by some individuals, on the one hand, and nonfeasance, on the other hand, that also results in non-use.

Included within the set of “covered persons,” *i.e.*, those entitled to immunity, are “program planners.” 42 U.S.C. § 247d-6d(i)(2)(B)(iii). A “program planner” is

a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b).

Id. at § 247d-6d(i)(6).

A program planner is someone who is involved in providing or allocating covered countermeasures. Program planning inherently involves the allocation of resources and when those resources are scarce, some individuals are going to be denied access to them. Therefore, decision-making that leads to the non-use of covered countermeasures by certain individuals is the grist of program planning, and is expressly covered by PREP Act

There are going to be circumstances where plaintiff pleads that defendant’s culpability is the result of its failure to make any decisions whatsoever, thereby abandoning its duty to act as a program planner or other covered person. Although this is a small hole through which to wiggle to avoid complete preemption, we are confident, were it not for two legal constraints, that it would grow as plaintiffs become more adept at fashioning their pleadings. However, “complete preemption . . . functions as an exception to the well-pleaded complaint rule.” *Giles v. NYLCare Health Plans, Inc.*, 172 F.3d 332, 336 (5th Cir. 1999). Thus, federal courts are free to entertain discovery to ascertain, for jurisdictional purposes, the facts underlying the complaint. *See United Surgical Assistants, LLC v. Aetna Life Ins. Co.*, 2014 WL 4059889, at *1 (M.D. Fla. Aug. 14, 2014) (allowing jurisdictional discovery on whether plaintiff’s claim was completely preempted by ERISA).

B. Fourth Amendment to the Secretary’s Declaration Supports the *Grable* Doctrine

In addition to complete preemption as the basis for article III jurisdiction and removal, the Court recognized a separate doctrine in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg.*, 545 U.S. 308 (2005). Under *Grable*, even in the absence of a claim arising under federal law, “a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues.” *Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg.*, 545 U.S. 308, 312 (2005) (emphasis supplied). Thus, a substantial federal question is implicated, for example, where “the

interpretation of a federal statute [] actually is in dispute in the litigation and is so important that it sensibly belongs in federal court.” 545 U.S. at 315. Here, ordaining the metes and bounds of PREP Act protection in the context of a national health emergency necessarily means that the case belongs in federal court. The Secretary, in his Fourth Amendment to his PREP Declaration, similarly concluded, when he stated that

[t]here are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng’g. & Mfg.*, 545 U.S. 308 (2005), in having a unified, whole-of-nation response to the COVID–19 pandemic among federal, state, local, and private-sector entities.

85 Fed. Reg. at 79,197 (col. c).

See also 42 U.S.C. § 247d-6d(b)(7) (“No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.”). As such, the secretarial determination provides the underlying basis for invoking the *Grable* doctrine with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure. Once invoked, the court retains the case to decide whether the immunity and preemption provisions apply; if they do not apply, then the court would try the case as it would a diversity case. If the court finds, though, that the PREP Act applies, it would dismiss the case or if death or serious physical injury proximately caused by willful misconduct is alleged, transfer it to the District Court for the District of Columbia. *See* 42 U.S.C. § 247d-6d(d)-(e).

II. Limitations

This Advisory Opinion may be supplemented or modified. It is intended to minimize the need for individual advisory opinions. This Advisory Opinion sets forth the current views of the Office of the General Counsel.³ It is not a final agency action or a final order. It does not have the force or effect of law.

Robert P. Charrow

Robert P. Charrow
General Counsel
January 8, 2021

³ *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647–48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 (“The head of an executive department . . . may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]”); *Statement of Organization, Functions, and Delegations of Authority*, 85 Fed. Reg. 54,581, 54,583 (Sept. 2, 2020).

Exhibit J

**UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF LOUISIANA
ALEXANDRIA DIVISION**

CLARA RACHAL

CIVIL DOCKET NO. 1:21-CV-00334

VERSUS

JUDGE DAVID C. JOSEPH

**NATCHITOCHES NURSING &
REHABILITATION CENTER LLC,
ET AL**

**MAGISTRATE JUDGE JOSEPH H.L.
PEREZ-MONTES**

MEMORANDUM RULING

Before the Court is a MOTION TO DISMISS (“the Motion”) [Doc. 6] pursuant to Federal Rule of Civil Procedure 12(b)(6) filed by Defendants, Natchitoches Nursing and Rehabilitation Center, LLC (“NNRC”) and Kacey Masters (“Masters”). For the reasons set forth below, the Motion is DENIED, and the parties are directed to engage in a period of limited discovery to determine whether the Plaintiff’s claims, or any portion thereof, are encompassed by the PREP Act, 42 U.S.C. § 247d-6d.

FACTUAL AND PROCEDURAL HISTORY

On April 29, 2020, after allegedly contracting COVID-19 while residing at the Natchitoches Nursing and Rehabilitation Center, Plaintiff Clara Rachal filed the instant lawsuit in the 10th Judicial District Court, Natchitoches, Louisiana, (“10th JDC”) against Defendants.¹ [Doc. 1-4]. In her Petition for Damages (“the Petition”), Plaintiff seeks damages resulting from Defendants’ alleged negligent and grossly negligent conduct in connection with her contraction of the virus. [*Id.*]. In essence, Plaintiff’s claims are premised on Defendants’ alleged failure to appropriately care

¹ Defendant Miranda Green did not join in the pending Motion to Dismiss because she had not been served with process in this lawsuit as of the date the Motion was filed. [Doc. 6].

for Plaintiff and take adequate precautions to prevent the spread of COVID-19. The specific allegations asserted against Defendants in the Petition are as follows:

- Failing to take timely, proper and effective actions to eliminate and/or minimize the risk for Ms. Rachal's exposure to COVID-19, aka Coronavirus;
- Failing to timely and adequately assess the risk for Ms. Rachal to COVID-19 aka Coronavirus, and to initiate an appropriate level of preventative actions, interventions and measures to prevent her exposure to and potential for contracting this virus;
- Failing to timely and properly monitor, detect symptoms, test, and diagnose Ms. Rachal for COVID-19 virus aka Coronavirus condition, or to make appointments with other healthcare providers for such services;²
- Failing to timely and properly provide or make available appropriate medical attention to Ms. Rachal for the Covid-19 virus aka Coronavirus condition;
- Failing to develop and implement a care plan with proper regard to the needs of Ms. Rachal;
- Deviation from the standard of care owed by defendants' staff, nurses, aides and other representatives of defendant to its physically and/or mentally impaired clients;
- Failing to do all things necessary and proper in the circumstances to reduce the risk of Ms. Rachal being exposed to and contracting COVID-19 virus aka Coronavirus resulting in the severe decline in her physical and mental conditions;
- Failing to exercise reasonable and proper judgment;
- Charting and documentation errors;
- Failing to initiate proper protocols to sanitize defendant's facility, including the areas of the facility where Ms. Rachal was located;
- Failing to appropriately train and supervise staff;
- Failing to adhere to the accepted standards of medical care required under the circumstances;

² The allegation concerning the failure "to make appointments with other healthcare providers for such services" is directed only toward the NNRC.

- Failing to properly follow and implement doctors' orders and care plans;
- Failing to properly follow and implement the guidelines and recommendations of the WHO, CDC, LDH, and common sense guidelines for taking care of elderly patients in a nursing home setting during a global pandemic.

[Doc. 1-4].

On February 8, 2021, Defendants removed this action on the basis of federal question jurisdiction, 28 U.S.C. § 1331. [Doc. 1].³ On February 15, 2021, Defendants

³ Concurrent with its filing of this Memorandum Ruling, the Court is remanding on timeliness grounds seven other related cases removed to this Court from the 10th JDC on the same date. *See, e.g., Herbert Beaudion, et al. v. Natchitoches Nursing and Rehabilitation Center LLC, et al.*, W.D. of La. Case No. 1:21-cv-00329. Plaintiff in this case, however, did not file a motion to remand and, accordingly, any procedural defects to this removal have been waived. *See Hinkley v. Envoy Air, Inc.*, 968 F.3d 544, 549 (5th Cir. 2020) (explaining that a plaintiff waives any objection to procedural defects if a motion to remand is not timely filed after removal). Notwithstanding Plaintiff's waiver of procedural objections, subject matter jurisdiction cannot be waived and should be considered when fairly in doubt. *See Ashcroft v. Iqbal*, 556 U.S. 662, 671 (2009). Because the Motion before the Court is dispositive as to the claims asserted and the Court has not elsewhere addressed the issue of subject matter jurisdiction, the Court will briefly address it here.

Defendants premise their removal to federal court on the contention that the Public Readiness and Emergency Preparedness Act ("PREP Act") is a "complete preemption" statute that creates federal question jurisdiction. [Doc. 1]. District courts across the country have examined whether the PREP Act is a complete preemption statute and have arrived at varying conclusions. *See e.g., Dupervil v. Alliance Health Operations, LCC*, 2021 WL 355137 (E.D.N.Y. Feb. 2, 2021); *Garcia v. Welltower OpCo Group LLC*, 2021 WL 492581 (C.D. Cal. Feb. 10, 2021). For the reasons that follow, the Court finds that the PREP Act is a complete preemption statute, thus creating a federal cause of action as specified therein.

To establish complete preemption for purposes of federal question jurisdiction, Fifth Circuit jurisprudence requires that a defendant must show: (1) the statute contains a civil enforcement provision that creates a cause of action that both replaces and protects the analogous area of state law; (2) there is a specific jurisdictional grant to the federal courts for enforcement of the right; and (3) there is a clear Congressional intent that claims brought under the federal law be exclusive. *PCI Transp., Inc. v. Fort Worth & W. R.R. Co.*, 418 F.3d 535, 544 (5th Cir. 2005). The PREP Act contains each of these elements as to claims falling within its scope. To illustrate this point, it is instructive to compare the principal components of the PREP Act and the Air Transportation Safety and System Stabilization Act of 2001 ("ATSSSA") passed in the wake of the September 11, 2001, terrorist attacks, which the Second Circuit held was a complete preemption statute. Pub.L. No. 107-42, 115 Stat. 230 (2001) (codified at 49 U.S.C. § 40101); *In re WTC Disaster Site*, 414 F.3d 352 (2d Cir. 2005). Instrumental to the Second Circuit's analysis was the ATSSSA's statutory components, which consist of: (i) the creation of a Victim Compensation Fund to provide relief, without

filed the instant Motion to Dismiss, contending that the PREP Act warrants either dismissal of Plaintiff's claims in their entirety or a transfer of this action to the United States District Court for the District of Columbia. [Doc. 6]. The Court heard oral argument on April 1, 2021, and the Motion is now ripe for ruling. [Doc. 12].

LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) allows a defendant to move for dismissal of a plaintiff's claims before filing its answer when the pleadings, on their face, fail "to state a claim upon which relief can be granted." A pleading states a claim for relief when, *inter alia*, it contains "a short and plain statement ... showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2).

litigation, to individuals (or relatives of deceased individuals) physically injured or killed as a result of the September 11 attacks; (ii) immunity to the airlines; (iii) a federal cause of action as the exclusive judicial remedy for damages arising out of the attacks; and (iv) an exclusive venue in the United States District Court for the Southern District of New York for all suits brought on that federal cause of action. *In re WTC Disaster Site*, 414 F.3d at 373. Significantly, the composition of the PREP Act is very similar in that it: (i) creates a Covered Countermeasure Process Fund to provide relief, without litigation, to eligible individuals for "covered injuries" directly caused by the administration or use of a "covered countermeasure;" (ii) provides immunity to "covered persons," except in the case of "willful misconduct;" (iii) creates an exclusive federal cause of action for damages against a covered person for willful misconduct; and (iv) provides that the federal court in the District of Columbia is the exclusive federal venue for suits on the federal cause of action. 42 U.S.C. § 247d-6(d); 42 U.S.C. § 247d-6(e).

Further, the PREP Act states that the remedy available in the Covered Countermeasure Process Fund "shall be exclusive of any other civil action or proceeding for any claim or suit this section encompasses," with the exception of the federal cause of action for damages against a "covered person" for willful misconduct. *Id.* § 247d-6(d). The Court concludes that, together, these provisions demonstrate Congress's intent that the PREP Act exclusively encompass "claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure." *Id.* § 247d-6d(a)(1). Accordingly, to the extent Plaintiff's alleged loss was caused by a "covered person" and arose out of, related to, or resulted from the administration to or the use by an individual of a "covered countermeasure," this Court has federal question jurisdiction to apply the provisions of the PREP Act.

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when it contains sufficient “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* Plausibility requires more than just the “sheer possibility” that a defendant acted unlawfully; it calls for enough facts “to raise a reasonable expectation that discovery will reveal evidence” to support the elements of the claim. *Twombly*, 550 U.S. at 556. Although the Rule 8 pleading standard does not require “detailed factual allegations;” mere “labels and conclusions,” or “a formulaic recitation of the elements of a cause of action” do not suffice. *Id.* at 555.

In ruling on a Rule 12(b)(6) motion, a court may rely on the complaint, its attachments, “documents incorporated into the complaint by reference, and matters of which a court may take judicial notice.” *Dorsey v. Portfolio Equities, Inc.*, 540 F.3d 333, 338 (5th Cir. 2008) (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007)). A court must accept all factual allegations as true and construe the facts in the light most favorable to the plaintiff. *Gines v. D.R. Horton, Inc.*, 699 F.3d 812, 816 (5th Cir. 2012). Further, “[a]lthough dismissal under rule 12(b)(6) may be appropriate based on a successful affirmative defense, that defense must appear on the face of the complaint.” *Kelly v. Nichamoff*, 868 F.3d 371, 374 (5th Cir. 2017) (quoting *EPCO Carbon Dioxide Prods., Inc. v. JP Morgan Chase Bank, NA*, 467 F.3d 466, 470 (5th Cir. 2006)).

LAW AND ANALYSIS

I. The PREP Act

Congress has delegated authority to “[t]he Secretary of Health and Human Services [to] lead all Federal public health and medical response to” national public health emergencies. 42 U.S.C. § 300hh. In executing this responsibility, the Secretary of Health and Human Services (“Secretary” or “HHS Secretary”) is tasked with promoting “[r]apid distribution and administration of medical countermeasures” in response to a public health emergency. *Id.* § 300hh-1(b)(2)(D). Passed in 2005, the PREP Act vests the Secretary with authority to determine that a disease or other threat to health constitutes a public health emergency and to issue a declaration recommending administration of specified countermeasures. *See id.* § 247d-6d(b)(1).

Once the Secretary has issued a declaration, the PREP Act provides broad immunity “from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure...” to “covered persons,” provided the Secretary has issued a declaration with respect to such countermeasures. *Id.* § 247d-6d(a)(1). This statutory immunity applies to damages resulting from the “design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use” of “covered countermeasures.” *Id.* § 247d-6d(a)(2)(B).

The PREP Act also establishes two avenues for recovery of damages from “covered injuries”: a compensation fund and an exclusive federal cause of action. The compensation fund, *i.e.*, the “Covered Countermeasure Process Fund,” provides “compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to such declaration.” *Id.* § 247d-6e(a). Additionally, for loss caused by “willful misconduct,” the PREP Act provides that “the sole exception to the immunity from suit and liability of covered persons ... shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct ... by such covered person.” *Id.* § 247d-6d(d)(1). This federal cause of action is required to be brought and maintained only in the United States District Court for the District of Columbia. *Id.* § 247d-6d(e)(1).

On March 17, 2020, in response to the COVID-19 pandemic, the Secretary issued the “Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19” (“Declaration”). 85 Fed. Reg. 15198 (Mar. 17, 2020). The Declaration essentially recommends the use of various covered countermeasures and provides PREP Act’s immunity and recovery mechanisms to covered persons for activities related to medical countermeasures against COVID-19.

Since its original issuance on March 17, 2020, the HHS Secretary has amended the Declaration seven times.⁴ Additionally, the Office of General Counsel for the HHS

⁴ See First Amended Declaration, 85 Fed. Reg. 21012 (Apr. 15, 2020); Second Amended Declaration, 85 Fed. Reg. 35100 (June 8, 2020); Third Amended Declaration, 85 Fed. Reg.

Secretary (“OGC”) has issued six advisory opinions clarifying the Secretary’s Declaration and subsequent amendments. In his Fourth Amended Declaration, the Secretary stated that “the Declaration must be construed in accordance with the Department of Health and Human Services (HHS) Office of the General Counsel (OGC) Advisory Opinions on the Public Readiness and Emergency Preparedness Act and the Declaration (Advisory Opinions). The Declaration incorporates the Advisory Opinions for that purpose.” 85 Fed. Reg. 79190 (Dec. 9, 2020).

II. Coverage of Plaintiffs Claims Under the PREP Act

Defendants argue that their Motion should be granted because the PREP Act provides them immunity from suit and liability in this forum. In the alternative, Defendants maintain that this action should be transferred to the United States District Court for the District of Columbia – the exclusive federal venue for suits on causes of action falling within the scope of the PREP Act. In order for this Court to grant the relief sought in this Motion, Defendants must prove from the face of Plaintiff’s Petition: (i) that Defendants are covered persons as defined by the PREP Act; and (ii) that Plaintiff’s claims against them are “for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.” 42 U.S.C. § 247d-6d(a)(1). For the following reasons, the Court finds that although the Defendants are clearly “covered persons,” it is not clear

52136 (Aug. 24, 2020); Fourth Amended Declaration, 85 Fed. Reg. 79190 (Dec. 9, 2020); Fifth Amended Declaration, 86 Fed. Reg. 7872 (Feb. 2, 2021); Sixth Amended Declaration, 86 Fed. Reg. 9516 (Feb. 16, 2021); Seventh Amended Declaration, 86 Fed. Reg. 14462 (March 16, 2021).

from the face of the Petition that the entirety of the claims at issue relate to Defendants' administration or use of covered countermeasures.

a) Covered Persons

A covered person under the PREP Act includes: (A) the United States or (B) a person or entity that is: (i) a manufacturer of [a covered] countermeasure; (ii) a distributor of such countermeasure; (iii) a program planner of such countermeasure; (iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or (v) an official, agent, or employee of a person or entity described in clauses (i), (ii), (iii), or (iv). *Id.* § 247d-6d(i)(2). Here, Defendants contend that they qualify as covered persons because they are program planners under subsection (B)(iii).

The NNRC is a skilled nursing facility licensed by the State of Louisiana. [Doc. 6-1]. Neither the text of the statute nor the Secretary's Declaration expressly includes skilled nursing facilities within the definition of "covered person." However, the OGC's October 2020 Advisory Opinion states:

[A]ny individual or organization can potentially be a program planner and receive PREP Act coverage. So for example, private businesses, public and private transportation providers, public and private schools, and religious organizations are all eligible for PREP Act coverage when they act in accordance with the PREP Act and the Declaration.

[Advisory Opinion 20-04, Doc. 6-9]. Moreover, the OGC has issued at least one opinion letter in response to a specific inquiry that concludes "senior living communities are 'covered persons' under the PREP Act when they provide a facility to administer or

use a covered countermeasure in accordance with the Secretary’s March 10, 2020 Declaration under the PREP Act.” This letter specifically provides:

[A] senior living community meets the definition of a ‘program planner’ to the extent that it supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including by ‘provid[ing] a facility to administer or use a Covered Countermeasure in accordance with’ the Declaration.

[*Id.*]. Thus, the Court deems the NNRC a covered person under the PREP Act to the extent it provided covered countermeasures to its residents.

Masters is a former Executive Director of the NNRC who was responsible for overseeing the facility’s day-to-day operations. [Doc. 6-1]. The Declaration clearly provides that a private sector employer or other person is considered a program planner when he or she carries out statutorily prescribed activities. [Doc. 6-3]. Masters is therefore covered under the PREP Act to the same extent as NNRC.

b) Covered Countermeasures

Next, the Court must examine whether it can decide, from the face of the Petition, whether Plaintiff’s claims relate solely to the Defendants’ administration of “covered countermeasures.” The PREP Act, in sum, defines covered countermeasure as a drug, biological product, or device that is a “qualified pandemic or epidemic product” or a “security countermeasure,” or is authorized for emergency use under the Federal Food, Drug, and Cosmetic Act. 42 U.S.C. § 247d-6d(i)(1).

In an Advisory Opinion published on January 8, 2021 (the “January 8th AO”) the OGC addressed the scope of the PREP Act with respect to covered countermeasures. [Advisory Opinion 21-01, Doc. 6-7]. Therein, the OGC took a broad

view of the applicability of the PREP Act as it relates to claims against nursing homes and other healthcare providers for failing to provide sufficient personal protective equipment (“PPE”) or adequate training on the use of PPE. *Id.* Notably, the OGC rejected the position adopted by some courts that if a covered countermeasure were not used, then there is no PREP Act immunity. [*Id.*]. The OGC did agree, however, that total inaction is not covered by the PREP Act. Importantly, the OGC stated that the PREP Act extends immunity to covered persons for anything “relating to” the administration of a covered countermeasure. [*Id.*]. According to the OGC, only in instances of nonfeasance, *i.e.*, where “defendant’s culpability is the result of its failure to make any decisions whatsoever, thereby abandoning its duty to act as a program planner or other covered person,” would complete preemption not apply. [*Id.*].

In examining whether Plaintiff’s claims relate to covered countermeasures, the Court finds that some deference to HHS’s interpretation of the PREP Act is appropriate, given: (i) the PREP Act’s broad grant of authority to the HHS Secretary; (ii) the Secretary’s express incorporation of the OGC’s Advisory Opinions into the Declarations for purposes of construing the PREP Act; (iii) the complexity of the relevant statutory provisions; (iv) the technical nature of the subject matter; and (v) the need for uniformity in the judiciary’s interpretation of the PREP Act across the United States. *See Chevron, Inc. v. NDRC, Inc.*, 467 U.S. 837, 843 (1984); *United States v. Mead Corp.*, 533 U.S. 218, 220 (2001) (“an agency’s interpretation may merit some deference whatever its form, given the ‘specialized experience and broader investigations and information’ available to the agency ... and given the value of

uniformity in its administrative and judicial understandings of what a national law requires”). The Court further finds that HHS’s interpretation of the PREP Act and its scope is reasonable. *See Kornman & Associates, Inc. v. United States*, 527 F.3d 443, 455 (5th Cir. 2008) (Reasonable agency interpretations carry “at least some added persuasive force” and may “seek a respect proportional to [their] power to persuade” where *Chevron* deference is inapplicable) (quoting *Mead Corp.*, 533 U.S. at 235).

If Plaintiff’s claims against Defendants relate to covered countermeasures, then the Defendants are immune from suit and liability in this forum and this matter must be dismissed. However, if all or some of the allegations do not relate to covered countermeasures, then the Court is without subject matter jurisdiction and must remand those claims back to state court. From the face of the Petition and at this stage in the litigation, the Court is unable to determine as a matter of law that each of the Plaintiff’s claims relate to “the administration or the use by an individual of a covered countermeasure.” Accordingly, the Court DENIES the Motion to Dismiss and orders the parties to engage in a period of limited jurisdictional discovery.


CONCLUSION

For the foregoing reasons, IT IS HEREBY ORDERED that Defendants’ Motion to Dismiss [Doc. 6] is DENIED.

IT IS FURTHER ORDERED that the parties are to engage in a 90-day discovery period, during which the parties are directed to conduct discovery as to the nature of Plaintiff’s claims, including Defendants’ specific acts of alleged misconduct

and whether such acts are “covered countermeasures” under the PREP Act. At the end of this discovery period, the parties are to submit briefing on the scope of the PREP Act as applied to the facts underlying Plaintiff’s claims.

THUS, DONE AND SIGNED in Chambers on this 30th day of April 2021.



DAVID C. JOSEPH
UNITED STATES DISTRICT JUDGE

Exhibit K

BURNS WHITE LLC

By: William J. Mundy, Esquire

Attorney ID #035981989

By: Brian D. Pagano, Esquire

Attorney ID #016812007

457 Haddonfield Road, Suite 510

Cherry Hill, NJ 08002

(856) 382-6006 / Fax (856) 382-6007

Attorneys for Defendant,

Laurel Brook Operator, LLC d/b/a Laurel

Brook Rehabilitation & Healthcare Center

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT COURT OF NEW JERSEY
TRENTON VICINAGE

PATRICIA WHITE, individually and as guardian of TARAR CASSEL and TARAR CASSEL,

Plaintiffs,

VS.

COMMUNITY OPTIONS, INC.,
VIRTUA WILLINGBORO HOSPITAL,
LAUREL BROOK REHABILITATION &
HEALTHCARE CENTER, POWERBACK
REHABILITATION – PISCATAWAY,
JON DOE #1-10 (fictitious) and ABC
CORPORATION #1-10 (fictitious)
(representing previously unidentified physicians
and medical providers),

Defendants.

: CIVIL DIVISION

: No.

DECLARATION OF VALERIE
LOWMAN IN SUPPORT OF
THE NOTICE OF REMOVAL OF
DEFENDANT, LAUREL BROOK
OPERATOR, LLC D/B/A LAUREL
BROOK REHABILITATION &
HEALTHCARE CENTER

I, Valerie Lowman, declare as follows:

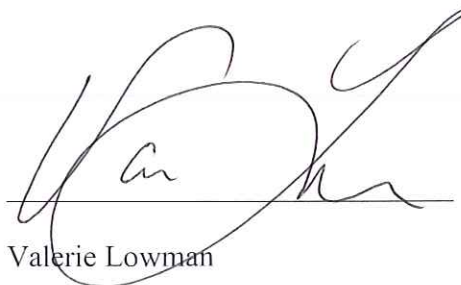
1. I am over the age of eighteen (18), capable of making this Declaration, and have personal knowledge of and can testify competently to the facts stated herein.

2. During the relevant time period alleged in Plaintiffs' Complaint, I was the Director of Nursing at Laurel Brook Rehabilitation & Healthcare Center (hereinafter "Laurel Brook").

3. During the COVID-19 pandemic, including the time period alleged in Plaintiffs' Complaint, Laurel Brook received guidance and mandates from various governmental agencies, including the federal Centers for Disease Control and Prevention (CDC) and Centers for Medicare and Medicaid Services (CMS), regarding protocols for long term care facilities such as Laurel Brook to respond to the pandemic, including infection control, testing, treatment, equipment and supply allocation.

4. Laurel Brook implemented COVID-19 countermeasures, including policies, procedures and practices, based upon these federal mandates and guidelines.

I declare under penalty of perjury that the foregoing is true and correct. Executed on September 7, 2021.



Valerie Lowman